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**HIT Policy Committee**

**Privacy & Security Workgroup**

**Public Hearing**

**Draft Transcript**

**December 8, 2014**

**Presentation**

**Operator**

Thank you, all lines are now bridged.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Thank you. Good afternoon everyone this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Policy Committee’s Privacy and Security Workgroup. This is a public meeting and there will be time for public comment at the end of the meeting. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. I’ll now take roll. Deven McGraw?

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Deven. Stan Crosley?

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information - Drinker Biddle & Reath, LLP**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Stan. Adrienne Ficchi? Bakul Patel? Cora Tung Han?

**Cora Tung Han, JD – Division of Privacy and Identity Protection, Bureau of Consumer Protection – Federal Trade Commission**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Cora.

**Cora Tung Han, JD – Division of Privacy and Identity Protection, Bureau of Consumer Protection – Federal Trade Commission**

Hi.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

David Kotz? David McCallie?

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, David. Deb Bass? Donna Cryer?

**Donna R. Cryer, JD – Principal – CryerHealth, LLC**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Donna.

**Donna R. Cryer, JD – Principal – CryerHealth, LLC**

Hi.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Gayle Harrell? Gil Kuperman?

**Gilad J. Kuperman, MD, PhD, FACMI – Director Interoperability Informatics – New York Presbyterian Hospital**

Present.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Gil. Gwynne Jenkins? John Wilbanks? Kitt Winter?

**Kitt Winter, MBA – Director, Health IT Program Office – Social Security Administration**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Kitt. Kristen Anderson?

**Kristen Anderson – Staff Attorney, Division of Privacy & Identity Protection – Federal Trade Commission**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Kristen. Linda Kloss?

**Linda Kloss, RHIA, CAE, FAHIMA - President at Kloss Strategic Advisors, Ltd.**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Linda. Linda Sanches?

**Linda Sanches, MPH – Senior Advisor for Health Information Privacy – Office of Civil Rights**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Linda. Manuj Lal? Mark Sugrue? Micky Tripathi? Sephania Griffin? Taha Kass-Hout? And from ONC Lucia Savage?

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

She was on, she just…

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Yes.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Was going to be on mute while she is…

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

And Helen Canton-Peters?

**Helen Canton-Peters, MSN, RN – Office of Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Helen. And Kathryn Marchesini?

**Kathryn Marchesini, JD – Acting Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Kathryn. Okay with that we’ll turn it over to you Deven and Stan.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

All right, great. Well, thank you very much, Michelle, much appreciated. Welcome to the Workgroup members as well as members of the public and our panelists for today to our second…the second day of the hearing that we are doing on health big data and policy frameworks to govern health big data. We had a terrific session last Friday and we have some more folks tee’d up to give us some presentations today.

Just a few administrative matters. For those of you who were not on our call on Friday if you are a Working Group member or one of our Federal Government Liaisons and you’re online you use the raise hand function that you’ll see at the top of your computer screen. There is a little figure with a hand raised to put yourself in the queue for the Q&A session.

We will also be sure, today, to deliberately ask for input from Workgroup members and, again, Federal Government Liaisons who are on the phone today but may not be online or may not have access to the raised hand feature. We’ll make sure to leave time during the Q&A session to see if you all have any questions.

So, if you’re someone who is joining us just by audio and you are part of our Working Group or a member of our Federal Government Liaison Team you’ll have an opportunity to ask questions even if you can’t use the raised hands function. So, we’ll do a better job this time of reaching out to you, to see if you have any questions.

Unfortunately, for members of the public we don’t have the capability to allow you to ask questions of the panel as well, but as we always do with any of our public sessions there will be some time left at the end of the call for public comment.

And in addition, you know, the hearings really are just the kickoff for our examination of these issues. We are going to be talking about what we’ve learned over these two sessions during a series of publicly open Working Group meetings and there will be other chances for the public to weigh in either, you know, during those calls or, you know, quite frequently people will send us things that they want us to take into consideration and we’re always open to receiving comments in writing as well.

So, with that, what we did on Friday to sort of kickoff the session was to sort of go over a bit of what the White House Report on Big Data, which said, about health in particular and then more recently, the announcement of a federal initiative to evaluate policy frameworks governing health big data and in particular, you know, to determine whether those frameworks are in fact robust enough to meet the demand of a bigger health data ecosystem where we really hope to maximize the opportunities to learn and to get more efficient and better at providing health and healthcare to the population but also address some of the concerns that have been raised.

So, rather than go through all of these slides again, since we did this on Friday, I’ll just note that we have pulled out, in this slide deck, which is available to the public, you know, relevant portions of both the White House Big Data Report, as well as this fact sheet on open government that specifically asks for stakeholder input on how federal laws and regulations can best accommodate big data analyses that promise to advance medical science and reduce healthcare costs.

Because, this charge here, which is actually on slide 4, is essentially why we are coming together to do these hearings and try to evaluate this issue as best we possibly can.

So, with that I’m going to turn it over to my Co-Chair, Stan Crosley who will be managing this panel because I’m actually giving a presentation. So, I’m going to take off my Chair hat and put my presenter hat on and listen to what our other presenters have to say today. Thank you.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

Thanks, Deven and welcome all. And our first speaker on our first panel here is Melissa Bianchi and Melissa is a Partner at Hogan Lovells and focuses her practice is on healthcare regulatory and privacy issues. Melissa, welcome, we’re pleased to have you.

**Melissa Bianchi, JD – Partner – Hogan Lovells US LLP**

Thank you. So, I’m going to walk through just for 5 minutes a high-level overview of a couple of the current laws that affect the uses of health data. So, we’ll start by talking about HIPAA and the research requirements. If we can go to the next slide.

So, just as a high-level list of a couple of the laws and other panels will talk more about others, obviously, we have HIPAA. In particular, the research requirements that the effect secondary uses of data. Also, the Human Subject Research Regulations, both under the Common Rule and from the FDA and I’ll talk briefly about those as well.

But there’s a whole host of other federal and state laws. And a couple to keep in mind that we aren’t going to cover today include the Part 2 Substance Abuse Regulations, which are the federal regulations that constrain the release of substance abuse information in certain circumstances, FERPA, which governs educational records and then obviously, state laws which in many states are focused on sensitive categories of data and often things like genetic information, mental health data, alcohol and substance abuse information and so forth. Next slide.

So, let’s just look a little bit at HIPAA. I think probably everyone participating is quite familiar with this but the Privacy Rule generally restricts the use and disclosure of Protected Health Information or PHI unless that use or disclosure fits within a permissible bucket. And the permissible buckets generally, under the rule, are treatment, payment and healthcare operations.

And healthcare operations, which Deven will talk more about, is really the only one of these that I think is an avenue for really research and uses of data. But it’s really focused on activities internal to a covered entity such as quality improvement.

In addition to treatment payment and healthcare operations, which are the big three, there are other permissions under HIPAA there are certain allowances for public health disclosures those are fairly

limited and certain allowances for disclosures that are required by other laws. I know this was the topic on Friday but HIPAA does allow...it doesn’t govern de-identified data, data that’s been de-identified in accordance with the safe harbor or the expert determination under HIPAA.

The safe harbor requires removal of 18 fields in order for the data to be de-identified and that often doesn’t give researchers the data they need to conduct the research they’re hoping to conduct and allow for the kind of quality improvement in the healthcare system that people are aiming toward.

There is also an opportunity under HIPAA for research purposes and a couple of other limited purposes to make use of a limited data set. It’s a little bit more robust data set than de-identified but not a lot and so again, may or may not be sufficient for the kind of uses that people are looking to make of the data for research purposes. And then always, you can use and disclose data pursuant to individual authorizations. Next slide.

In terms of research, this is the definition and Deven will talk again about this of research under HIPAA and also under the Common Rule. There are several ways under HIPAA that you can use data for, identifiable data, for research purposes, again, pursuant to the authorization.

You can also get a waiver of an authorization by an IRB or a privacy board. I mentioned limited data sets and de-identified information. And then there are a couple more narrow uses, certification for reviews, preparatory to research and special provisions for decedent information. Next slide.

And so I think some of the most…there have been a lot of changes following the HITECH Final Rule that I think have really taken…I guess given us additional opportunities with respect to research and I think definitely a move in the right direction. The permission for future research is one of those. Historically, it was not possible to get someone’s authorization for future unspecified research.

Following the HITECH Rule an authorization may now permit future research as long as that authorization form adequately describes the future research such that it would be reasonable for the individual to expect that his or her protected health information could be used or disclosed for that purpose. So, drafting those forms is quite an art because you want to make sure that somebody is reasonably on notice but you also want to be broad enough because you don’t necessarily know what that future research will be, you know, and really because you don’t know what you’ll find in this first round of research for example. So, I think how it works in practice is still very much feeling our way in that.

And then let’s…I think the compound authorization requirement, which I’ll talk about very briefly, also affects, you know, the drafting of those forms and really what kind of authorization can really be obtained that will allow for meaningful consent for future research. So, let’s go to the next slide, which is on compound authorizations.

And again, you know, pre-HITECH Final Rule…well, first of all the Privacy Rule generally prohibits compound authorizations. But historically it has prohibited compound authorizations in a way that could have had the effect of making research and future research, in particular, harder to do.

The final rule did, again, fix that piece, to some extent and it does permit, now, compound authorizations for research purposes in certain circumstances and it has to do with whether the authorization differentiates between the conditioned part of the research like a clinical trial which you have to sign the authorization in order to get the treatment because the treatment is only being offered via the clinical trial and the unconditioned part of the authorization, which may be say for your data to go into a data bank for future research.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

And Melissa…

**Melissa Bianchi, JD – Partner – Hogan Lovells US LLP**

Yes?

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

I know that time is completely inadequate to describe the difference between compound authorization and future things. So, in the question and answer I’d like to follow up on that.

**Melissa Bianchi, JD – Partner – Hogan Lovells US LLP**

Absolutely.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

But, we’re just about out of time here.

**Melissa Bianchi, JD – Partner – Hogan Lovells US LLP**

Yes, no, I’m racing through these.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

Okay.

**Melissa Bianchi, JD – Partner – Hogan Lovells US LLP**

Yes, we can definitely talk more about that. And then let me just mention the Common Rule, because I know I’m already at my five minutes, in the next slide and just, you know, mention that the Common Rule again uses that same definition of research and it applies to any entity conducting federally funded research and institutions that are operating under a federal-wide assurance that say that they’re going to adhere to the Common Rule regardless of where their funding comes from and it applies to research involving an individual, a living individual about whom your dealing with data and identifiable private information.

The FDA, if the research is for purposes of getting something approved via the FDA’s approval processes then the FDA Human Subjects Research Regulations also come into play.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

Right, thanks so much Melissa.

**Melissa Bianchi, JD – Partner – Hogan Lovells US LLP**

Yes.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

And we will come back no fear on questions.

**Melissa Bianchi, JD – Partner – Hogan Lovells US LLP**

Great.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

Let’s move to Deven McGraw is going to talk now and you heard Deven just a few minutes ago and Deven is a Partner in the Healthcare Practice of Manatt, Phelps & Phillips.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Oops, sorry on mute, okay, thanks a lot, Stan. If can just get Altarum to advance me to my first slide that would be great. Thank you.

So, I’m going to dive into something that Melissa mentioned a bit in her presentation that is really a deeper dive into some pieces of HIPAA that…and it’s relevant to do this because the Privacy and Security Working Group back when we called it the Tiger team, actually did explore this issue a bit and put some recommendations forward that were blessed by the Health IT Policy Committee on this issue and I think it’s important for the Working Group members, as well as members of the public, to understand where we landed on a set of issues that, in fact, maybe relevant to big data considerations that we are engaged in.

So, healthcare operations, which is a category of activity under HIPAA, covered entities and their business associates can engage in without needing to get patient authorization or consent first and they don’t…and while they’re subject to minimum necessary standards they’re not necessarily, again, subject to consent nor do you have to use de-identified or a limited data set for them, although you certainly could.

There are a couple of categories of healthcare operations that, as Melissa mentioned, look a lot like research uses. They include conducting quality assessment and improvement, including outcomes evaluation and development of clinical guidelines as long as obtaining generalizable knowledge is not the primary purpose of studies that are resulting from these activities. And operations also include population-based activities that are relating to improving health or reducing healthcare costs and development of protocols.

In contrast to that, research is a systematic investigation including research development, testing and evaluation that is designed to develop or contribute to generalizable knowledge. And the Common Rule, which Melissa mentioned, which covers federally funded research, has the exact same definition for research. And when something isn’t research it’s not regulated by the Common Rule. So, you know, when there are operations, you know, that doesn’t constitute research.

So, you’ll notice here that the distinction is really, is the purpose or the primary purpose of what you’re doing of the underlying analytics. Is it designed to contribute to generalizable knowledge becomes this very important sort of line drawing exercise.

And so as a result, something I’ve called the paradox in HIPAA, which is the two studies that use data for quality improvement purposes using the same data points done to address the same question or sets of questions and done by the same institution will be treated as operations if the results are not intended to contribute to generalizable knowledge, which a lot of entities conclude means if you’re using it only for internal purposes. But treated as research if you intend to share the results with others so that learning may occur.

And some guidance that was issued by the Office for Civil Rights many years ago, when these rules… around the time when these rules were first promulgated, allows you to sort of have a later change of heart, you know, you discover something…you originally planned to do it as an internal operation’s activity but you, you know, found something very interesting in your data and you want to be able to share it, but certainly if you set out from the start to be…trying to contribute to generalizable knowledge you’re going to end up in the research bucket is the conclusion that at least I draw from the rule.

And a question gets raised about, how does this treatment really advance the learning health system as well as protections for data. Because the line drawing occurs with respect to what you intend to do with the results and not necessarily how you handle the underlying research project or the data.

And so as a result we did look at this, as I mentioned earlier, and this was in the context of an advanced notice of proposed rulemaking, so really, a request for information from the public about some potential changes to federal research rules. So, it wasn’t an opportunity to opine on HIPAA, per se, as much as

it was an opportunity to opine on the Common Rule, which again, those are two separate rules, although many entities could be subject to both.

And what we said was, you know, if you’re using clinical data, so data in an electronic medical record or a health plan record in order to evaluate the safety, quality and efficacy of care, you know, you really should treat that like we treat healthcare operations under HIPAA even if you’re intending to share what you learn for generalizable knowledge as long as the HIPAA entity, the provider maintains oversight and control over the decisions about data use, just as we would expect them to do for healthcare operations.

And those entities should certainly follow the full complement of fair information practices when they’re using identifiable protected health information for these purposes. But that this reuse of data doesn’t…unless you are raising the risks by moving the data into a place that isn’t as protected as your own institution, that merely because you’re trying to contribute to learning that itself should not trigger greater regulatory oversight.

And we did acknowledge, as a group, that there might be circumstances where, you know, just a mere reuse of the clinical data in an electronic record would need to trigger greater scrutiny, but certainly, that this line should not just be drawn at the place of, you know, well we intend to share the results for generalizable knowledge.

And so there’s a link at the bottom of the slide to the actual letter that we submitted as part of the public comment period and, you know, you do have, you know, some of the changes to the research rules under HIPAA that Melissa began to talk about that do…you know, are an attempt to make a bit

easier the research, you know, the ways that we reuse data in a clinical or a claims record for purposes of contributing to generalizable knowledge, but it’s not entirely clear that we’ve taken a sufficient number of steps to make sure that, you know, when we’re putting protections on data, with respect to

reusing it for valuable purposes, we’re doing so in a way that doesn’t penalize people or create disincentives to contributing to the knowledge base for healthcare in the US, but that we’re addressing what the real risks could be of doing that.

And so, you know, I have a few slides here that’s sort of talk about what we might be able to do to fix this paradox whether it’s, you know, providing more guidance about when consent or authorization rather under HIPAA could be waived or whether there is a modification of the rules that might be due.

And then also to think about, you know, if we’re going to impose some greater regulation on reuse of data that has greater risk, what are the factors that trigger greater risk? Does it involve a loss of control over the information whether that’s physical control or whether that’s contractual control, you know, the ability to control how the data are used, how sensitive is the data.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

We’re going to have to come back to all the rest of these ones, Deven.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

All right, you’ve got it, I figured I was close to time. I meant to time myself and then I forgot.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

Yeah, yeah I gave you some latitude to finish the slide.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

I know you did.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

But we are…but I will…we’ll come back again, as to Melissa we’re going to be coming back with some questions.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yeah, that’s fine.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

So, I think that’s been tee’d up already.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

And we can go to Kirk.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

All right, all right, and our final speaker on this panel is Kirk Nahra and Kirk is a partner with Wiley Rein and he’s Chair of the Firm’s Privacy Practice and Co-Chair of its Healthcare Practice. Kirk?

**Kirk Nahra, JD – Partner - Wiley Rein LLP**

Thank you very much. What we’ve heard so far on this session, and let’s go to the next slide, please, is where HIPAA might be able to be changed to improve some of the goals with big data. I’m going to sort of talk about the flip side of that which is where HIPAA doesn’t cover data that we’re talking about.

I think everyone realizes that HIPAA has never covered all healthcare data. It’s a regulation that came out of a statute that was written for other purposes and we sort of accidentally end up with a Privacy Rule but we’ve always known there have been gaps.

What we’ve seen in the past few years is an explosion in what’s covered by those gaps, we’ve got mobile applications, websites, personal health records, wellness programs and sort of a variety of situations where we’ve got more and more healthcare data that is not subject to the HIPAA rules.

At the same time, we’ve seen healthcare entities, who are covered by HIPAA, using a much broader range of what I would consider non-health data for healthcare purposes, we’ll talk about that a little bit later, but we’re finding all kinds of companies who are using data that’s not normally thought of as healthcare data, you know, the kinds of magazines you read, the clothes you buy, whether…your grocery habits, etcetera and bringing them in for healthcare purposes. So, what I’m going to focus on is the protections available for this Non-HIPAA data in the context largely of big data. So, let’s go to the next slide, please.

One of the first options is to figure out how the Federal Trade Commission fits into this environment. Federal Trade Commission has become, essentially, a default regulator of privacy and security over the past decade or so. The Federal Trade Commission relies on primarily the Federal Trade Commission Act.

There are, you know, a handful of statutes, including some we’ll talk about in a minute, where the FTC is given specific authority, but the FTC has very general authority under the Federal Trade Commission Act and it has broad authority to prevent unfair or deceptive acts or practices.

Now for the most part, there aren’t regulations in this area that’s just a statute that the FTC has had for

something like 100 years at this point. Using that authority the FTC has become very active on general enforcement of data security standards. They’ve brought approximately 50 cases over the past decade covering a wide variety of substantive areas some of them, a handful have been healthcare cases, usually they’ve been other kinds of entities.

There is at least a debate as to whether the FTC really has authority to do this. There are two cases pending in federal court right now which are challenging the ability of the FTC to regulate data security essentially those cases take the position that the FTC doesn’t have explicit authority and they’re sort of making it up as they go along. Now there’s obviously a good counterpoint to that and the FTC has been winning so far but that’s data security.

In the area of privacy they haven’t done the same kind of activity, particularly in the healthcare area. There have been a handful of privacy related cases, maybe more than a handful, but they have mainly been, you know, situations where a party has said something and then that turned out not to be true. So, let’s go to the next slide and we can talk about that for a minute.

It is clear that FTC can take enforcement actions against statements that aren’t true. That can be, you know, deceptive advertising, there’s a whole bunch of areas that have nothing to do with what we’re focused on today.

It’s clear that if the company says, for example, I am going to collect healthcare data from you and I will only use it for purposes A and B and then in fact they use it for C, D, E and F that where they say things that aren’t true the FTC clearly can take action there.

The more general question, the tougher question is whether there is a broader ability of the FTC to go after unfair practices in the data privacy area and then you have the question of what exactly would those be. So, the FTC Act is out there as a possibility. But right now it’s only going to be used in pretty extreme circumstances, particularly those where there has been some kind of misstatement. Let’s go to the next slide, please.

Another statute, which again is out there in this area, is the FCRA or Fair Credit Reporting Act which is a statute that’s been around for, I don’t 40 or so years at this point, it regulates consumer reporting agencies primarily, not just consumer reporting agencies, but primarily consumer reporting agencies in connection with three very specific areas, credit, employment and insurance.

The idea was if you are applying for credit for example there are regulations on how those credit reports that the banks and other people use to evaluate your credit status, there are rules on how that information is gathered, how they’re used, what people have to tell you about what’s in those reports, etcetera.

We’ve seen a little bit of a patchwork being built to deal with some kinds of medical information. There were changes to that rule a few or to that statute a few years ago. For example, there is now consent required from individuals in order to report substantive medical information in connection with these purposes. They’ve had to do some carve-outs for debts that are medical related. If you owe a debt to a hospital they don’t really treat that all that much differently than owing a debt to your grocery store or somewhere else.

There are also prohibitions on using medical information for credit purposes. You can’t essentially deny someone credit because they have a disease. Again, with that exception for debt, but if we go to the next slide I think it’s fair to say that the FCRA is relevant and important in the situations where it applies, but that it applies only in very limited situations.

So, we have the possibility of the FTC, but again, no clear standards. FCRA is important, but very limited relevance. Melissa mentioned state law, which there are lots and lots of state laws but it’s confusing, it’s and often outdated, very seldom enforced.

And so what we see are substantial open gaps for data that is not clearly within the healthcare or within the HIPAA structure. And even within the HIPAA structure it’s becoming harder and harder to find what healthcare data really is. So, let’s go to the next slide, please and let’s just talk quickly about sort of where we can go.

It seems to me we have a couple of big picture options. You can obviously do variations on this. You could have something specific to deal with Non-HIPAA healthcare data. You could have something that covers all healthcare data, sort of a general HIPAA idea that could be changing HIPAA or it could be something else or you could have our broader overall privacy law that basically says we can’t really figure out what healthcare data is anymore so we’re going to regulate this more generally.

So, that’s the approach that we’ve got out there sort of the problems that are out there and I think the challenge for people who are thinking about this issue is that we have more and more data that is clearly health-related information that is outside the scope of the HIPAA rules and for the most part, with limited exceptions, for the most part is not really regulated by existing law, at least any kind of law that is specific to practices dealing with that Non-HIPAA data. So, Stan let me stop at that point and turn it back to you.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

That’s great and right now we don’t have any hands raised that I see, but I have plenty of questions and I also want to go back and use the prerogative here to allow Deven to wrap up her last couple of slides and then I’d like to ask some questions I certainly have tee’d up and others on the Workgroup may join at that point. Deven, did you want to go through your last two slides we kind of cut you off there?

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yeah, no, I think…well, right and if there are things that Melissa didn’t get a chance to present too.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

Yes.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

You know, I think, essentially, what I was saying is that if we, you know, sort of following onto what we did as a group previously, while, you know, acknowledging that line drawing based on, you know, what you intend to do with the results isn’t necessarily…might not be the right place to draw that line. Then where do you regulate more heavily, i.e., you know, more often ask for an authorization in circumstances were identifiable data are to be used, require IRB approval of research questions, which is part of the requirements of the Common Rule, you know, when do you sort of pull those triggers and when can you treat something more like operations?

And so one of the…you know, one issue is, you know, is it really…does it have all the hallmarks of being internal just like operations in the sense that it’s sort of under the control, whether that’s a physical control, the data doesn’t leave the HIPAA covered entity, or it’s what might be called contractual control, right, it might be possessed by someone else, but the circumstances of use are tightly controlled under a contract may be something similar to a limited data set data use agreement.

And so that in other words, it’s not that the data goes out the door and, you know, we have less control over its subsequent use. When you have those kinds of controls and also where you’re dealing…maybe there’s a data sensitivity line drawing exercise, you know, more sensitive categories of data, such as those that might be covered by state law, data on vulnerable populations like prisoners or children for example.

And then, you know, fair information practices, which, you know, are the hallmarks of data stewardship and have really been the anchor for so many of our recommendations in the past, which includes openness and transparency about data use, data minimization, you know, collect and use only what you need, security safeguards and having some overarching accountability and oversight, you know, consent is one potential fair information practice but it doesn’t trump all and, you know, you deploy that consent in circumstances where it’s necessary but it’s not the default.

You know, when you have other fair information practice principles being…you know, as part of either your policies or practices, you know, does that create a risk lessening mechanism that means, you know, we don’t necessarily have to have a cookie-cutter approach and require necessarily IRB approval or consent for each individual question.

So, that was just, you know, it’s something that I have done some writing on, you know, it’s not something that I…you know, others have written on this topic, as well. These are not just I think ideas unique to me and I think they provide some food for thought about how you structure a policy framework going forward for, you know, reuses of data where we’re really trying to maximize what we’re getting in terms of public benefit from every health data point that’s collected and maximizing that while having some responsible and accountable way for doing that. That was a really long-winded answer, but that’s essentially it.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

No, well and for those who have been on the call or were on the call on Friday there is a consistent theme that kind of emerges is that, you know, the data, you know, wherever it is and however it’s used security and the primary aspects of FIPs should be applied, especially that around data security and data

control and data access. So, I think that’s consistent with what you are saying. I think you’re taking that a step further to kind of blending in healthcare operations and research which makes a lot of sense.

Melissa, I also cut you off as you were kind of wrapping things up. I do have specific questions for you but if you had a wrap up comment or two that would be okay.

**Melissa Bianchi, JD – Partner – Hogan Lovells US LLP**

Well, I mean, I think I made it through my slides, you know, obviously, at a very quick pace. So, if you have specific questions why don’t we just dive into those?

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

That’s great because…and this is really for all of you, but, Melissa is the topic speaker on compound authorizations and future research and I know you’re going to hate me for asking this question but at times this can start to get a little bit confusing.

Perhaps we can start with, you know, what was the idea behind changing both compound authorizations and future research language and you think we’ve advanced down that path and have you had experience in giving guidance to companies and trying to help them understand where the line is between, you know, research that is so far in the future that it becomes a compound authorization potentially or maybe the use of specimens where it could be considered a future use for a compound…they just seem a little bit gray between the two sometimes.

**Melissa Bianchi, JD – Partner – Hogan Lovells US LLP**

Right, I mean, look I think what HHS was trying to do was to ease the rules somewhat for research. I think they heard loud and clear from the research community about challenges that researchers felt they were facing and dealing with HIPAA, and in looking at these authorizations and what kinds of consent they were allowed and not allowed to get from individuals. So, I think it was really an effort to move the ball forward and I think that it did.

I think that, you know, just to talk a little bit more about what the compound authorization rules are, you know, generally, under the Privacy Rule you can’t combine an authorization for one purpose with an authorization for another purpose, right, and at its core that makes sense, right, because you want people to understand what they’re authorizing and not muddy the waters by asking them to consent to too many things at once.

But there is an exception for that now for research where you can have an authorization for use or disclosure of PHI for a research study that is combined with any other type of authorization for the same research study or for another research study.

And, you know, so, you can combine…you know, it gives you more leeway in terms of the consent that researchers can seek when getting, you know, with respect to different research studies. So, you could, for example, get consent for an initial research study and get authorization for the creation of a database or a research repository. And that’s a really important, you know, edition.

The Privacy Rule also is complicated in that there is a prohibition on conditioning authorizations, which, again, makes sense from a consumer protection stand-point is that you can’t condition the provision of treatment on payment and healthcare plan enrollment and so forth on the sign and give an authorization, you can’t make someone sign an authorization for example to get treated except for in a clinical trial context and again there is an exception for that where you’re conditioning research related treatment and also getting an additional, like a research repository type consent.

I think where it gets tricky is in the future research and how those compound authorization rules work with the future research rules, which only are now in the preamble language at the final HITECH Rule. And what does it look like to permit future research and to get an authorization that adequately describes future research, such that it’s reasonable for the individual signing the authorization to expect that their information would be used or disclosed for that purpose and how do you do that in combination with a compound?

And I think, you know, you…yes, I have worked with companies to draft those and it’s tricky to do so. I think, you know, there is a way to do it. You know, you still need two signatures in most cases. And, you know, I mean, I don’t think we’re all the way there, but I think that these changes in the HITECH Rule have made it easier for researchers to get the kind of consent that they are seeking.

You know being reasonably specific about the future research isn’t always that easy and doesn’t always facilitate the research you didn’t know about until you did the first research study and learned from that experience what might be the next most helpful step but you draft that language and try to balance being reasonably specific but broad enough to do the next stage even though you can’t really anticipate what all those stages will be.

**Kirk Nahra, JD – Partner - Wiley Rein LLP**

Stan, this is Kirk I’d add one other point on that which is I think those changes are sort of a good example of some of the tension that we see in the policy debate. There are really two things that I think were being balanced in those changes.

There was the desire to, you know, ease some of the burdens created by HIPAA in connection with research for the benefit of doing more research. At the same time, they’re obviously thinking about the patient impact and I think part of what drove that change was essentially a desire to let patients in fact agree to more.

The way the rules were set up before, you were almost were in a situation where researchers had to keep going back to people asking their permission and there was a little bit of a tendency to say, well, if somebody just wants to authorize it for future use let’s just let them do that.

So, it was actually a situation where you had sort of both of those goals pointing at least to some extent in the same direction but that balance is always going to be the challenge, you know, we’re trying to improve research, we’re trying to streamline some of the negative impacts of the rule but at the same time you want to make sure that the patient’s side of it is protected.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

Yes, let me pause for a second and see if we have comments from the Workgroup and Government Liaison members on the phone only. Is there anybody on the phone only who had a question? If not, I’ll move onto my next.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Hey, Stan, this is Lucia, can you hear me?

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

Yes, please, Lucia?

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Good, I have one question it’s for the panel in general. So, one of the things we heard a lot about on Friday was both the ability, the ability of big health data to both provide phenomenally helpful information particularly to address disparities but at the same time information that was federated in these techniques could be used in very…in ways that had negative impacts on particular communities.

And I’m an old person. I remember redlining so I’m just going to call it data redlining for lack of a better way to describe it. And I was wondering since we have these very well experienced, these experienced lawyers on the phone could you talk to us about what exists today to address that ability of data to be used in ways that is not for the benefit of the whole population or has negatively impacted certain populations. And if there isn’t something sufficient today, what are models we could look at to build those controls with?

**Kirk Nahra, JD – Partner - Wiley Rein LLP**

Sure, this is Kirk, let me jump in on that. I mean, I think there is, you know, what that question goes to is the sort of, you know, purpose or ultimate impact of the data rather than the data itself. And you could certainly draw some analogies from the Fair Credit Reporting Act where it says, you know, you can build all this data but you can only use it for particular kinds of purposes and if you use it in a way that has an adverse impact on an individual you have to disclose certain things to them. That’s one sort of model.

I mentioned the gaps that we had in HIPAA going back to the beginning of HIPAA. I think one reason we didn’t worry that much about the gaps originally is that a lot of the gaps where in areas like, you know, insurance products that weren’t health insurance where there is an enormous body of existing regulation that is really isn’t privacy regulation, but it’s regulation dealing with how decisions are made about people in connection with insurance.

And so, I think, one of the models we could move to in a big data environment is to define rules about how the data is used a little bit more, but I think the challenge there is to sort of define, you know, good things versus bad things and could you…you know, for example, could you use data…you know, and we’re seeing this debate with wellness programs right now.

We want to encourage behavior and we want to reward good behavior in connection with wellness programs but there’s been a concern that the corollary to that is you don’t want to…we’ve made a judgment that you don’t want to punish people for some kinds of bad behavior. Now, again, we could debate the merits of that and maybe the line has been, you know, we haven’t been able to reward the good enough, but I think that’s the challenge right now.

We certainly have rules, most of them aren’t really privacy rules that define behavior, you know, you can’t discriminate against someone in health insurance pricing because they’ve had this kind of condition, but we’re now bringing it into the privacy debate when we’re seeing all this data that’s being used for all these purposes and we really don’t have any regulatory structure around it.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

Okay, I have a fairly…it’s kind of a follow-up to this question and that is, you know, Kirk you mentioned it with FCRA and then some of your three main options that we could consider on how to address data that wasn’t within the covered entities sphere, but I think just in general if the panelists have any comments on what they think is the most significant privacy or data security issue that isn’t currently addressed that would need to be addressed.

And then kind of working along those lines I think is probably a natural conversation around is there a framework to this. Is FCRA a framework that could be applied to a, you know, broader context since we’re talking about appropriate use types of activities?

**Kirk Nahra, JD – Partner - Wiley Rein LLP**

Well this…yeah, this is Kirk, let me jump…I mean, I think FCRA is a tough one because...and I guess it’s not a model I think you can broaden out very much because it’s very tailored to particular circumstances and I just don’t think it extrapolates very well.

I think you could easily use some of the principles that are in the HIPAA rules right now and have it cover a broader range of data. I mean, for example, I mean the core, you know, if you were going to sort of put aside some of the, you know, more minimal elements of HIPAA, some of the tangents, the core of HIPAA is the idea that for these core healthcare purposes, treatment, payment, health care operations, you know, consent is essentially assumed, you have particular defined things that are public purposes where information can be disclosed for other reasons and then you need patient permission for everything else. That’s a model you could extrapolate to all kinds of other data sources, that doesn’t have to be limited to covered entities.

I think the challenge is going to be…you know, what we have now with the big data environment and all this unregulated data is that it’s flowing through so many different people, so many different entities you have to sort of start defining principles on people who don’t necessarily have a direct relationship with the individual.

But I think the HIPAA model could be broadened out. Now again, you’d have to define covered entities in a much broader way, but even some of the states have tried to do that. I mean, the Texas law, which I don’t like for a lot of other reasons, but Texas basically said, we’re going to take anyone who touches healthcare data and we’re just going to call them a covered entity now.

You could have a model that covered, you know, that essentially protected the data rather than the HIPAA model, which is it protects the data if it flows through a particular kind of covered entity. I think that’s the, you know, that’s the scope limitation that came through the statute that doesn’t fit today’s environment where that same data is being generated by all kinds of other people it’s not just doctors who generate that data.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Right.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

And Melissa or Deven?

**Melissa Bianchi, JD – Partner – Hogan Lovells US LLP**

And this is Melissa, yeah, I mean, I guess I think that I would caution against using, you know, kind of extending HIPAA to a broad range of other entities but I think some of the same kind of concepts or principles at least with respect to big data uses and research sort of broadly defined, you know, especially as we look at efforts to improve the healthcare system, all of the health reform initiatives designed to do that and then the constraints on getting the data necessary to actually accomplish that.

So, you know, but I think as Deven mentioned, sort of the FIPS approach and looking at some sort of baseline security requirements, things like that, for the kind of uses that we’re talking about in the sort of big data space, you know, may give more comfort and thus better enable the use of the data, you know, than the system we have today.

I mean, I do think there are some questions around how you define the scope of what health data is generally to Kirk’s comments about wellness programs and the kind of information that gets pulled into making insurance decisions about individuals or wellness programs. But I do think that there are some sort of general principles and including, you know, use the data you need and not more than that and sort of data use agreement type concepts that may be helpful.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yeah, I find, this is Deven, I find myself in pretty good agreement with both Kirk and Melissa on this. It sounded like both of them have counseled us and if I’m putting words in their mouth I’m sure they’ll correct me. Both of them have counseled us, you know, this sort of HIPAA for all kind of approach where we just take this regulatory framework that was designed to accommodate and acknowledge the sort of customary data flows of healthcare providers and health plans, and healthcare clearinghouses to mention another covered entity that doesn’t get mentioned very often.

You know the rules were designed for them and to just sort of presume that this kind of approach is necessarily going to work very well, if at all, in an environment for all health data I personally think wouldn’t be a good idea, it sounds like, you know, both Melissa and Kirk seemed to be saying also, you know, nice idea or maybe not so nice idea but it doesn’t necessarily work.

But looking to the fair information practices, which informed HIPAA, which informed data protection laws internationally, you know, really feels like the right way to go. And then I think it’s just how much do we…if we have that as a framework for health data and data that may not be health data on its face, but are put to a healthcare use and still probably need some work on that definition but that might be one direction to head in that, you know, do we tell people how to apply the fair information practices or do we just require them to have their own policies that address that?

And are there certain aspects of data use that we want to be able to consistently hold people accountable for like the, you know, the sort of discrimination, data redlining issues that Lucia brought up and how do we, you know, tend to address those because we just don’t have a way necessarily of doing that.

And it’s not always really easy to figure out, even if you decide that you can engage in that kind of, what’s a bad use of information line drawing to sort of say what that is sort of very clearly in health gets quite complicated, because, you know, just because a company may commercially gain from the use of data doesn’t necessarily mean there aren’t also financial or recognizable benefits to the public from that data use.

I mean, I bring up this example quite frequently, you know, if you have a pharmaceutical company that discovers a block buster drug and uses the data to help be more efficient in getting that drug out to patients who would need it, is that necessarily a bad thing, is it a good thing, is it a mixed thing?

**Kirk Nahra, JD – Partner - Wiley Rein LLP**

Well and Deven this is Kirk, let me just add one other point to that. I think, just to go back to Lucia’s question, I mean, I think it’s fair to say, I mean maybe I’m missing something, but I think it’s fair to say that HIPAA doesn’t address any of those sort of discrimination questions. What I mean by that is HIPAA gives you categories of things that you can do, let’s say data analytics just as an option or the quality improvement kinds of things you’re doing. They don’t say whether you’re going to use that for good quality improvement or bad quality improvement. They say you can do it for quality improvement.

So, the idea of making a substantive judgment under HIPAA is not something that HIPAA tried to do. It talked about categories, but not the sort of judgments within those categories. The Fair Credit Reporting Act and certain other kinds of laws, which again are not privacy laws for the most part, have often tended to go to sort of the merits of what you do with the information. But I think we would have to really do a very different model, we’d have to not use HIPAA as a model if you were going to go into a evaluating, you know, the sort of good judgments and the bad judgments.

The part I like about HIPAA, which I think we could extend, and as both of you have said, is part of fair information practices, is the concept that certain kinds of uses and disclosures are presumed to be normal. They may not be the same, may not be TPO if we’re talking about Non-HIPAA data, but the idea that certain uses and disclosures are normal and expected, and consent is presumed. Certain other uses and disclosures have a societal benefit and then everything else would need individual permission. That’s the sort of model I could see, taking from HIPAA, again, we’d have to play with the entities and we’d have to define what those are, but I think that’s the model that could be a useful version going forward.

I think it’s very hard to use HIPAA as a model for saying, this kind of analytics is good another kind of analytics is bad, we’ve just said analytics is appropriate.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

This is David, I have a question, I don’t know if…

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

Yeah, David, I was just going to call on you.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Okay.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

David McCallie?

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Yeah, just I think you probably have already answered my question, but this is may be more toward Kirk than anyone but anyone should feel free to jump in. I wrote down two things just listening to you, one is, you know, specifically, get permission for those behaviors that go beyond what we consider routine and normal or may benefit society on the one hand. And then on the hand, is this notion of prohibiting discriminatory behavior. And I’m curious of the tension between those two.

When you look at something like redlining in the financial sense or the Affordable Care Act and a pre-existing condition or GINA with genetic information and the success of those is targeted at prohibiting discriminatory behavior. So, what is the balance between focusing on the prohibition of bad behavior versus the enumeration of allowable behaviors?

**Kirk Nahra, JD – Partner - Wiley Rein LLP**

Yeah, and again, I think the idea of authorizations and permission in HIPAA isn’t…I mean, I don’t know that you can sign an authorization that says, I hereby give permission for my data to be used to discriminate against me. I mean, I’ve never…you know, we just…the sort of good and bad activities by…you know, how the covered entity uses the data, whether they use it for ill or for good isn’t really part of the HIPAA model at all.

And so I think if we were going to bring in this idea of, you know, the redlining idea, writ large, obviously, if we were going to incorporate that into some kind of a privacy law, healthcare privacy law, that would really be a new step as part of a privacy law. I mean, I’m just…

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Right.

**Kirk Nahra, JD – Partner - Wiley Rein LLP**

I’m stretching to figure out if there is…I mean, I’m not saying there’s nothing out there right now, but it’s just that it’s not part of HIPAA at all.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Yeah.

**Kirk Nahra, JD – Partner - Wiley Rein LLP**

It’s not really part of anything else that I can think of. Again, that’s not at all to say it’s not a good thing to do it’s just we deal with that now in other laws that aren’t really privacy laws that go to the sort of merits of what companies can do.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Yeah and I think, this is David again, I didn’t mean to imply that you had to force it into HIPAA. I was really asking about is it a good idea zoomed out…I mean, we clearly prohibit discrimination and discriminatory uses of data in the number of other sectors. You know we concluded in our session on Friday that all data is health data essentially or it can be in certain contexts.

So, is there, you know, is the thing that’s missing a framework for broader thoughts about prohibitions of the harms that come from data being applied to your health or your wellness or your illness? And maybe that’s a framework that’s missing from our current, you know, HIPAA and the Common Rule cover permitted uses but don’t really cover the non-permitted abuses, if I can coin a phrase.

**Melissa Bianchi, JD – Partner – Hogan Lovells US LLP**

And this is Melissa; I mean, I guess, I wonder if it wouldn’t be helpful in thinking about that to really catalog the laws that, you know, like GINA, like a number the Affordable Care Act contains a number of nondiscrimination provisions that really come at in a number of different areas. And I wonder if…you know, I think before doing that you’d want to identify the potential problem and the scope of it and what laws are out there now that may already prohibit those activities and where might there be gaps.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Right.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

That’s a great suggestion for the Workgroup.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Yes.

**Kirk Nahra, JD – Partner - Wiley Rein LLP**

The one example that comes to mind is the recent provision in HITECH that dealt with the individual’s ability to, you know, pay for services themselves and then tell the provider not to disclose that to the payer. I mean, that was a really interesting provision which, you know, I can understand arguments on sort of both sides of having that provision.

But basically, that seemed to be a provision that essentially said we don’t trust the health insurers to do what other laws tell them they have to do so we’re going to give the patient’s right to keep information from them. That was an interesting mixing of the sort of the ultimate results and the privacy kinds of issues.

You know my first thought was, well the, you know, the health insurers are already heavily regulated and what they can and cannot do with that information, you know, why would we alter that through a privacy law, but, you know, that was the choice that was made. And, again, I can sort of get it but that was sort of a mingling of those two ideas and it may be the only place in HIPAA that we really have that mingling.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

We have a question, Gil Kuperman?

**Gilad J. Kuperman, MD, PhD, FACMI – Director Interoperability Informatics – New York Presbyterian Hospital**

Yeah, this is Gil Kuperman here and, you know, so I think the majority of my questions have already

been kind of answered, you know, one was just to the extent that healthcare data can be distinguished from just data in general and it sounds like that was maybe covered on Friday, when unfortunately I couldn’t be on the call.

But, let me just…I have a quick question for Deven and the letter that was sent in 2011 kind of arguing for this, you know, operational perspective on, you know, what might be considered research uses of the data if it’s for, you know, safety, quality improvement things like that. You know just by way of context how was that received in 2011? And I’m just wondering if there was any pushback on that approach, you know, was there, you know, was there…you know, what was the basis for any pushback that might have happened at that time?

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Sure. So, we, you know, came up with the nuts and bolts of that letter as part of the Privacy and Security Tiger Team. We also had some assistance in helping us think through the issues raised by the advanced notice of proposed rulemaking. We had help from Dr. Richard Platt of Harvard Pilgrim who we asked to sort of join us as kind of almost an ad hoc member for our deliberations. He was incredibly helpful.

But you’re right to ask sort of where the pushback was. And so when we were discussing these issues with the bigger Policy Committee a number of folks who are, you know, where part of academic medical centers said, you know, I don’t want what I do to be called operations. I am conducting research. I feel like I’m conducting research when I do these things and I don’t think…they didn’t think the answer was to necessarily call something that involves the re-examination of clinical data in order to, you know, contribute to knowledge to not be considered to be research because that…you know, my understanding at the time was that this would have a lot of potential consequences with respect to, you know, there’s an entire enterprise built around valuing research uses that if you just sort of start moving the labels around could actually have some consequences.

You know the other point that was made was that journals, academic journals that are frequently the place where research, published research gets acknowledged out in the community and then disseminated, that the journals sort of operate based on the regulatory context of, you know, this is research that we’re publishing and they frequently will require you to have had institutional review board approval and to sort of acknowledge how you have dealt with the ethical issues that arise with respect to human subject’s research and that kind of research includes research where, you know, you are…it just involves the reuse of identifiable data.

So, we got pushback along those lines, but I don’t think anybody really disagreed with the idea that we shouldn’t be…that the line that distinguishes between when we regulate something more heavily and when we do not based on whether or not you are going to share what you learn, I don’t think that issue was in dispute.

**Kirk Nahra, JD – Partner - Wiley Rein LLP**

Deven, this is Kirk let me add one other point which is I think that the idea that Deven’s floating is an important and useful solution, but it’s only part of the problem. I mean, what that really does is deal with covered entities sort of doing their own analytical activities.

It wouldn’t really change the research, the true research, because those people are not business associates. They don’t want to be business associates and it really wouldn’t make sense for them to be business associates.

So, again, it would be an incremental solution, I think it would be a useful solution and it would address the sort of, you know, unexplained line that’s drawn in the rule right now but it doesn’t really get to the bigger, you know, the question of the true independent researchers who are doing this on their own coupled with all the things Deven just added about, you know, changing the label. So, that would be a useful change but it would only deal with a limited piece of this.

**Gilad J. Kuperman, MD, PhD, FACMI – Director Interoperability Informatics – New York Presbyterian Hospital**

This is Gil Kuperman, I appreciate that. I guess, you know, in the context of a learning health system and if we’re expecting the providers to be, you know, introspecting and, you know, generating knowledge based on their experience and then bringing that knowledge forward for the benefit of many, you know, so these would be kind of taking operational organizations and allowing them to disseminate their findings more easily as opposed to, you know, someone who kind of calls themselves a researcher and, you know, gets academic funding. It may assist that, but I see the multiple flavors here. I appreciate the feedback. Thank you.

**Claudia Williams, MS – Senior Health & Health IT Advisor – Office of Science & Technology Policy – White House**

This is Claudia at OSTP. I just wanted to circle back to one of the conversations earlier in the conversation about FTC and potential use of that authority to regulate or provide some enforcement capability.

And, you know, there have been conversations in different circles about some kinds of set of best practices for patient facing devices that could be tied to research uses and others accompanied with, perhaps, a more robust or, you know, active involvement from them in enforcement.

And I’m just interested to hear people’s thoughts about that pathway. There was a previous comment that that’s not really the approach now and I’m not…I don’t think I caught why that was.

**Kirk Nahra, JD – Partner - Wiley Rein LLP**

Sure, this is Kirk, let me jump in on it. I mean, the FTC has built, in the data security area, basically through its enforcement, a set of standards that I think is reasonably feasible for people to be required to follow now.

There are two court cases that basically say you made that up and you’re just…you know, you don’t have authority under the FTC Act to make up what data security safeguards are appropriate. The FTC has done that and they’ve been successful at it and I think they’re ultimately going to win the court cases.

The question would be, could they start tomorrow and go into a mobile…you know, a healthcare, you know, a fitness App for example, and say you told the truth to your customers about what you were

going to do with data, but something you’re doing is so inherently unfair that we’re going to decide that you violated the FTC Act because you, you know, sold their data to a fitness magazine, I don’t know, you’ve got to make up what that is. So, that’s the challenge.

And the FTC, so far, at least in their public activities, hasn’t shown any indication to try to start building from scratch that set of principles. I think it’s really hard to do and I think they’re more likely to be challenged by, you know, the companies who were targeted for that than they were when they were building data security because when they were building data security companies already had big security breaches and they sort of…I think, you know, just sort of reading into this, they sort of felt they had to go along.

**Claudia Williams, MS – Senior Health & Health IT Advisor – Office of Science & Technology Policy – White House**

Can I just…I guess I was speaking about a different angle which is…

**Kirk Nahra, JD – Partner - Wiley Rein LLP**

Okay.

**Claudia Williams, MS – Senior Health & Health IT Advisor – Office of Science & Technology Policy – White House**

To actually to have companies post really helpful and robust privacy policies that might be subject to enforcement. So, a slightly different…

**Kirk Nahra, JD – Partner - Wiley Rein LLP**

Well, yeah, no, I mean, right now I think, you know, most companies are building those privacy notices whether they are robust or useful is a very different judgment.

And I think the question…you know, right now I think, you know, I’m going to overgeneralize the law, but I think it’s fair to say that if I’m a…I’m one of these Non-HIPAA entities and I’m collecting healthcare data, if I put in my privacy notice essentially, here is everything I’m going to do with your data and it’s everything imaginable I can think of and if you buy my product I’m going to do that with your data, I think they’re allowed to do that for the most part.

And so the question I think, ultimately, is going to be, are we going to tell them whether it’s the FTC deciding or there is a new law that there are certain things you just can’t do. Right now I don’t think those limits really…I don’t think those limits are out there.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

Okay, we are at time for our session and so I want to thank again Kirk and Melissa, and Deven. And I think we are rolling right into our next session at this point. Deven, did you want to have a break or do you want to roll right into your…

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Why don’t we go ahead and get started if only because, you know, we have two people…

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

Yes.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

On the line who, you know, were probably counting on us running this as we…

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

That’s great, I’ll let you take it away then.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yeah, okay, great, thanks, Stan. We were unfortunately not able to be joined by Linda Avey from…who is a Co-Founder of 23andME and a company called Curious or Curios, Incorporated. We will reach out to her and reschedule her for another time that the Privacy and Security Working Group meets and we’ll proceed with our two other panelists today.

You know the one good news story about being one panelist down is that I think when I time both or our panelists in terms of their five minutes I’ll take a little bit of latitude and give them some additional time to finish up their presentations.

And then after we have the Q&A period for this next panel, which is another panel on health big data opportunities we will take a break for those of you who are hoping for one soon it’s coming. All right, so our next presenter is Kald Abdallah. He works with Project Data Sphere. He is the Chief Project Data Sphere Officer and I thank you Kald for joining us and I don’t recall if you…did you have slides?

**Kald Abdallah, MD, PhD – Chief Project Data Sphere Officer – Project Data Sphere, LLC**

Yes, do you have my…

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

You do, okay, there they are. When you want to advance them just say “next slide” and our technical folks will take care of that for you.

**Kald Abdallah, MD, PhD – Chief Project Data Sphere Officer – Project Data Sphere, LLC**

Sounds good. So, hearing the discussion and I would just like to disclose that I am a physician working on clinical research for oncology over the last 14 years. So, I’m not a lawyer. I hope to…

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

So, it will be a refreshing change from the last panel, thank you.

**Kald Abdallah, MD, PhD – Chief Project Data Sphere Officer – Project Data Sphere, LLC**

I’ll try to be as helpful as possible in the discussion. So, basically, I will try to stick to my five minutes, this is a very brief overview of what is Project Data Sphere, which is a nonprofit organization that is an independent initiative from the CEO Roundtable, which is also a nonprofit organization. Next slide.

So, the CEO Roundtable is a nonprofit organization that founded in 2001 by the 41st President, George Bush, and the task for that organization was to come together many…aggregate many different organizations from private, nonprofits and other institutions to work together in order to support innovation in cancer and cancer research, and cancer prevention.

Basically the challenge was to accomplish together what no single organization might consider alone. And there is a large number of different corporations and institutions that are part of the CEO Roundtable including all levels and others and also pharmaceutical companies. So, next slide. May I have the next slide? It’s not changing on the web I don’t know why.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

It changed on my end, this is Michelle.

**Kald Abdallah, MD, PhD – Chief Project Data Sphere Officer – Project Data Sphere, LLC**

Okay.

**Caitlin Chastain – Junior Project Manager – Altarum Institute**

Which slide do you need to be on right now?

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Check what our team did, is it the right slide?

**Kald Abdallah, MD, PhD – Chief Project Data Sphere Officer – Project Data Sphere, LLC**

Yeah, it is, on my screen it’s still on the second slide but I have it here on my computer. So, basically over the last four years what the team did in terms of trying to figure it out from the CEO Roundtable discussion about the idea of sharing data, what we need to accomplish to do that. That idea came about in 2011 in a regular meeting of the CEO Roundtable.

And in that discussion the idea of sharing clinical trial data from oncology trials, especially Phase III trials, came out and over the last three years there was a series of discussions and meetings, and the organization came together to address one of those obstacles after the other questions about privacy, legal, resources and also the optimal template and technological platform to have that data shared. So, the product, the output of that effort was the launch of Project Data Sphere website on April 8, 2014. So, next slide.

So, this slide, the Project Data Sphere Initiative, basically what is that initiative? What are we trying to achieve? This is an independent, voluntary, not-for-profit initiative. The website is a place that you can share, integrate and analyze cancer trial data from any source academic, industry.

The data sets available at the time of the launch was provided by seven different organizations, SANOFI, Celgene, Pfizer, AstraZeneca, Johnson & Johnson, Bayer and Memorial Sloan-Kettering and we are actively discussing with many other institutions and organizations that are working to share data with Project Data Sphere.

Since the launch we more than double the volume of data we have on the website. We have about 18 data sets, now and we have around 50 data sets committed to be shared before April of next year. So, we hope to multiply by five the volume of data by the time we achieve 1 year after the launch.

The data is de-identified. It is comparator arm data from large Phase III clinical trials. Also, the content is CFR and other data dictionaries and protocol. This enables any research to understand the data and explore the data for different research purposes.

Since the launch, we have received between 260 to 270 requests to access data. So, right now, we are close to 300 registered users in our website and the website is being hosted by one of the members of the CEO Roundtable which is SAS. So, SAS takes the responsibility of organizing and putting the structure behind the technology that supports the data and the website. Then also we have a mechanism on the website to allow researchers to connect with each other. Next slide.

So, on the slide about people, processes and technology, just an illustration about how the data provider provides data and what is the legal framework and how this was built and then on the other side, how registered users can access that data and how the platform is in the middle orchestrating that.

And the last slide, just two points, about how can this…how can we help using data that is not being used at all by organizations to advance cancer research. And I think the first thing we need is to stimulate the sharing of that data. There are thousands of clinical trials that are not being used at all by organizations and is just staying in warehouses and data sets being stored in computers and that data has a huge potential to advance cancer research.

And also what we need to do is once that data is shared is to stimulate and create mechanisms to support researchers that have access to that data to talk to each other and learn from each other fast in an environment that is productive and inductive to innovation in cancer. So, basically, this is a high-level overview about what is Project Data Sphere.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Great, thank you very much Kald that was really helpful. We’ll go to our next presentation but definitely hang on the line because we’ll open it up for Q&A after the fact. So, next we have Ella Mihov?

**Ella Mihov – Director, Healthcare Team - Ayasdi**

That’s right.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Oh, great.

**Ella Mihov – Director, Healthcare Team - Ayasdi**

Great.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Ella leads the Healthcare Practice for the Customer Value Team at Ayasdi which is a Silicon Valley startup with the mission of understanding the world’s data. It sounds like a big mission. Are you…did you…did we upload slides for you Ella or are you…

**Ella Mihov – Director, Healthcare Team - Ayasdi**

Yes, we did, just a few slides and I think we have them up already so we’re all set.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

All right so just let us know when you want to advance them.

**Ella Mihov – Director, Healthcare Team - Ayasdi**

Okay, great, will do. Well, thank you so much for this opportunity, I’m very glad to be able share a little bit about our company. So, I’ll give you a high-level of what we do and what we have been working on within healthcare. So, just as a background, we are a startup in Silicon Valley with the mission of making, as you said, the complex data out there useful and valuable and if you can just go to the next slide, please.

We were started by an investment by DARPA and NSF back in 2000 when these government agencies observed that scientific advances were really coming from the analytics and insight based on analyzing complex data, not necessarily through the collection of that data. But they noticed that they investing in data collection not really the analytics.

So, they decided to invest in the beginnings of the technology that really was our company, which came out of Stanford’s Mathematics Department. And they saw the promise of our technology to analyze data in a novel way where the shape of the data really allows the data to speak for itself to show an analyst as to where to even go to look for potential hypothesis in the data.

So, we’ve been working across several industries like financial services as well as public sector, life sciences, oil and gas and healthcare. And our same software that helped find, for example, upstream oil for oil and gas companies, also helps inform trading strategies in Wall Street and helps find fraud and waste in healthcare. We are even working with BHS on actually helping improve baggage handling and security. So, if we go to the next slide, please.

We’ve been seeing the analytics adoption curve play out in other industries and we’re seeing how healthcare is behind, but very much catching up. It’s actually…healthcare is now our biggest vertical at our company. And if you can just advance the slide, I think there is a visualization on it, maybe…yeah, that’s perfect, thank you.

So, in the past couple of years many healthcare organizations we’ve seen have the collected data, their data whether it’s patient generated data or EMR data, or claims data, which was in itself, and continues to be in itself, a major accomplishment, to build up the mark, the enterprise data warehouse and really put the data in a place that can’t even be analyzed.

And then we saw some of them with advanced organizations moved to perform very basic analytics such as, you know, now that I have the data how am I doing, how am I benchmarking against myself? And then we’ve seen how basically some of the most advanced organizations are now, for the first time, facing and tackling the problem of data complexity and real deep data analytics from claims data to EMR data, to patient generated and device data and it’s really coming at an unprecedented pace with unique analytic possibilities generated by each one of these data sets as well as by the combinations of these data sets which really leads to the theme that we are seeing for next year and projecting for next year, which is the theme of complexity, really.

And if we go to the next page, so using our software we’ve been focused on several use cases within healthcare based on the data that we’ve been able to analyze. So, in terms of the main use cases we’ve been targeting payers, healthcare payers and providers and our software leverages a concept called

topological data analysis and it’s essentially…it is a mathematics concept that allows one to see the shape of their data and the specificity with which we show the shape of data drives that insight and value and action ability. So, let me explain.

So, one example is we’ve been working with a 45 hospital health system to analyze their claims for understanding how to prevent and really remedy denials, so denied claims. So, we’ve been helping

them understand, from looking at all of their claims in one place, having a global view of them and also a local view for analysis to determine the root cause of those claims from maybe upstream processes that involve maybe wrong job titles or wrong processes that need to be fixed.

So, we have been helping understand the unique combinations of let’s say time of day procedure, physician and facility that might lead to denials. And because of the multivariate nature of such a problem our software platform actually allows for very quick understanding of what that unique combination is that might lead to denials.

So, we’re also looking at claims data for a large healthcare insurance company to also understand not denials, but the other side of that coin which is potential fraud, potential waste and potential abuse. So, I am going to now just highlight the other use cases not go into them in detail but, you know, we also have strength analyzing highly complex EMR data and we’ve been working with a hospital system called Mercy Hospitals on reducing clinical variation and applying lean principles to identify and fix instances of poor clinical outcomes. And they’re projecting over 100 million in savings over the next 3 years by just addressing two dozen procedures in the inpatient setting.

So, we’re, as you can see, doing a lot of different things in healthcare and we see that there is a major analytical shift happening that there is more appetite for such deep analytics including in places like or in use cases like population health management. So, if we go to the next slide, please.

We also believe that, kind of a lasting comment, that data analytics will be very much a great challenge for healthcare in 2015 and beyond and it’s really going to be that deep analytics that will allow for real progress to happen to understand, you know, how, for example, how the spending on Medicare and Medicaid can be optimized to really get to reduction of waste in the system, which can be as much as

30%, as well as, really understanding patients in a way that’s almost like a 360-degree view based on the data that can be generated by those patients across the care continuum. So, thanks, that’s it and I look forward to answering any questions later on.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Oops, on mute, thank you very much Ella we appreciate that. I don’t have any hands cued up yet, so I’m going to go ahead take the moderator’s prerogative and ask you to maybe explain once again, because I’m not a…I don’t want to say I didn’t do well in math that would be not of interest to anyone, whether it was true or not, but I don’t think I really get when you say the structure, like having, you know, examining the structure of the data and what sorts of insights that this yields.

And you gave a couple of examples, which I do think are going to be helpful, but, maybe if you can just take a little bit more time and elaborate on what you mean by that?

**Ella Mihov – Director, Healthcare Team - Ayasdi**

Absolutely, yeah, no, happy to. So, the way that we think about data and the way we analyze data using our software really starts with a data set of rows and columns and we apply hundreds of machine learning algorithmic combinations on that data to understand the correlations between the features, the variables and then like the row headings.

Like, let’s say patients for example, you have patients as the row headings and you have information about this patient which is basic information but it could also be very complex information about their genetics and that could be millions of column headings, each standing for like a specific gene for example.

And we take that data and we essentially apply all these algorithms to that data in a way that is very much…this is the beauty of our technology is that we apply a mathematical concept of topology to define a notion of similarity between all of the data points in the set and we visualize, through topological maps, the result of that analysis. And these topological maps essentially show you how connected different patients are based on their criteria and descriptors.

So, for example, we’ve been working with Mount Sinai on visualizing their population of diabetes type 2 patients and they had really unique data. They had genetic data as well as clinical data on almost all of those 20,000 patients and so we were able to upload that data and see, as a result, essentially like a heat map of where…by looking at the color and color being let’s say an expression of maybe an insulin related gene, which signaled that this patient was diseased with diabetes, we would actually see the hotspots of different groupings of patients which suggested to the researchers and to us, us being not domain experts and just coming from a mathematician’s stand-point, that information, that visual suggested to everyone who saw it that there was a continuum of diabetes type 2.

There were different subtypes of disease it wasn’t just all one because not all the patients that had the disease could be grouped together. They actually had very big differences that could all be summarized in different ways. We saw over one dozen different groups that naturally popped up out of the data.

So, in a way, the differences between traditional analytics and our type of analytics, is that we start with the data and not with a hypothesis.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Right.

**Ella Mihov – Director, Healthcare Team - Ayasdi**

We really let the data provide a hypothesis.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Got it.

**Kald Abdallah, MD, PhD – Chief Project Data Sphere Officer – Project Data Sphere, LLC**

Yes.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

So, I actually…thank you, that was actually really helpful.

**Ella Mihov – Director, Healthcare Team - Ayasdi**

Yeah, sure.

**Kald Abdallah, MD, PhD – Chief Project Data Sphere Officer – Project Data Sphere, LLC**

Kald here, may I…just a comment?

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yes, absolutely.

**Kald Abdallah, MD, PhD – Chief Project Data Sphere Officer – Project Data Sphere, LLC**

Yes, so I think two points here that I believe are crucial in the way we are observing after we begin to share data and I completely agree with the comments. One is you begin to expose the data to experts that traditionally have no access to that data.

So, once you begin to share data you see mathematicians, for example, we had several learnings about folks looking into the clinical trial data and showing how, for example, to apply mixed mathematical models and other things that traditionally is not within the expertise or the routine of a cancer researcher. So, then, you see the data being exposed to experts that usually have no access to that data that’s one thing.

The second thing is most of that data was created through a hypothesis driven mechanism. So, you have a hypothesis, you design a trial and you generate the data and then you do the analysis of that data and you pretty much are done with that data.

Now, the paradigm of looking into the data first and then beginning to understand different findings and correlations that you didn’t think about in a hypothesis driven research and you do when you’re doing data driven research.

So, I think there is a shift on the way you look into the data and use…find things that are unexpected and we are having a lot of surprises seeing the type of uses that we are seeing and this is just a few months with very limited number of clinical trial data and despite that we have several cases where you see uses that you didn’t anticipate and those are generalizable data, and information and knowledge, and very normative and so just two comments on that.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Terrific.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Deven, it’s David.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

I hear you David do you want to ask a question?

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Oh, yeah, good I wasn’t sure the hand raising mechanism was working so I was butting in.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

It may not be I’m going to go to just calling on people and I hear you and so go right ahead.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Okay, great.

**Linda Kloss, RHIA, CAE, FAHIMA - President at Kloss Strategic Advisors, Ltd.**

And Linda also.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Okay, great, Linda, you’re next.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

A couple of tightly related questions, which I know violates our rules, but to both our panelists, how did you get the data in terms of the legal mechanism?

It sounds like both of you are using de-identified data and if you could confirm that and confirm that it comes through the HIPAA Safe Harbor mechanism or is there some other mechanism, that’s question number one.

**Ella Mihov – Director, Healthcare Team - Ayasdi**

Yes.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

And then question number two is do you…have you normalized the data and melded it all altogether or is each data set kind of treated separately?

**Ella Mihov – Director, Healthcare Team - Ayasdi**

Yeah, that’s a great question. I’ll jump in and confirm that we are using de-identified data, you know, we are very much focused on making sure that everything is HIPAA certified.

In terms of your second question though, in terms of putting the data together, I would say that is one of the biggest areas of effort when it comes to getting the…in healthcare getting the data ready for analysis, getting it into one place where it’s not just normalized but really set up in a way that we want to analyze it through our technology.

And what we found was once we do that upfront work, subsequent data sets are really easy to upload and as new data comes in it’s really all about continuous improvement and making the analysis outcome be more and more refined and valuable to the users but really there is an upfront investment into what we call the…I guess the transformation and the loading…the extraction, the transformation, the loading of the data.

**Kald Abdallah, MD, PhD – Chief Project Data Sphere Officer – Project Data Sphere, LLC**

Hi, Kald here, so following on your questions, the first one, yes, we are using de-identified data. The responsibility for the de-identification process is on the data provider. They own that process so they review everything but most of them are using expert determination and not Safe Harbor but they are following the HIPAA laws in terms of the de-identification but this is on their side and they do this process.

And the second question is about…I’m sorry, what was the second question?

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Whether you normalize the data before you…and merge it together or do you treat each one of your data set as independent?

**Kald Abdallah, MD, PhD – Chief Project Data Sphere Officer – Project Data Sphere, LLC**

Yes, we post the data sets independently. But remember that this is clinical trial data and it differs from genomic data or patient claims, or health claims. This is highly structured by nature in general. Of course each trial is a little different.

But for example, we have several efforts ongoing right now where we are integrating many data sets in one large data set. This process is not so complicated as other forms of data. Clinical trial has a predefined approach on how the data is collected, described in the protocol. The data is collected as per CRF so the standardization and the aggregation of many clinical trials is a little simpler, not easy, but a little simpler than, for example, other types of data.

But we don’t have the data aggregated yet. We have several efforts working on that because we recognize that after sharing data having the data in a user-friendly format in a way that you can quickly transform that data into knowledge is a crucial next step.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Great. Linda Kloss?

**Linda Kloss, RHIA, CAE, FAHIMA - President at Kloss Strategic Advisors, Ltd.**

Yes, thank you. My question, actually, logically follows the last question particularly Kald on your slide where you referred to the opportunity for secondary analysis. And I was wondering whether there are specific privacy, security or governance mechanisms for that secondary use of the clinical trial data.

**Kald Abdallah, MD, PhD – Chief Project Data Sphere Officer – Project Data Sphere, LLC**

Yes.

**Linda Kloss, RHIA, CAE, FAHIMA - President at Kloss Strategic Advisors, Ltd.**

How do you contemplate that being sort of stewarded?

**Kald Abdallah, MD, PhD – Chief Project Data Sphere Officer – Project Data Sphere, LLC**

Yes, so the data is voluntarily shared by the data providers and they reviewed informed consent and all the other information and they went through the process of de-identification and then they provided that. So the entire analysis, from a legal perspective, was provided by the data provider.

So, for example, when Pfizer provided their data they went through this process with their own legal and support, they have their own structure. So, I am not going to respond in terms of details from each one of the data providers.

All the data analysis we are doing is secondary. This is not planned on the original protocol. This is de-identified data that we are using from clinical trial cancers and we are exploring different knowledge and different answers, in terms of scientific questions based on that data. But the original purpose of that data was described on the protocol and that’s not what we are doing. We are not really reproducing the research that was done before. We are exploring that data in new ways.

And we had a lot of discussions with patient advocacy groups and patient representatives. And there is a sense, in the oncology community, that it’s very important to extract as much knowledge as possible from all available data considering how deadly is this disease and how impactful it is for the patients and their families. So, that was the thinking behind how we structured the way we are doing the data sharing and we are seeing a lot of innovation coming from that data analysis which is secondary in nature. I hope I answered your question.

**Linda Kloss, RHIA, CAE, FAHIMA - President at Kloss Strategic Advisors, Ltd.**

Yes, just one clarification. My assumption is that some of that secondary analysis might actually combine data sets from more than one clinical trial?

**Kald Abdallah, MD, PhD – Chief Project Data Sphere Officer – Project Data Sphere, LLC**

Yes. Yeah we are. For example, one of the efforts we are working on is a crowdsourcing challenge where we are trying to build algorithms to predict mortality and predict drug discontinuation in patients with prostate cancer. And this is…we are aggregating three data sets and we’re going to post that data and try to crowd source the data to find the answers to predict which patient is going to benefit from the therapy and which patient is going to discontinue from the therapy because of toxicity for example, one of the questions we are posting.

**Linda Kloss, RHIA, CAE, FAHIMA - President at Kloss Strategic Advisors, Ltd.**

Thank you.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

I have Gil next up and then Lucia. Go ahead, Gil.

**Gilad J. Kuperman, MD, PhD, FACMI – Director Interoperability Informatics – New York Presbyterian Hospital**

Thank you. This question is mainly for Ella Mihov although the other presenter may have some thoughts. What I’m wondering, Ella, is when you work with your healthcare clients as compared to your non-healthcare clients are there any additional hassles or frustrations, or burdens that are imposed by, you know, health privacy laws, you know, or regulations that, you know, kind of in contrast to non-healthcare, you know, are there, you know, are there barriers that are presented by the current regulatory environment that, you know, if the environment was different you would see more opportunity or something like that? I hope that makes sense.

**Ella Mihov – Director, Healthcare Team - Ayasdi**

Sure, yeah, that does. It’s a really great question. Typically, because we originally actually started out working a lot with life-sciences and financial services and now have been much deeper in healthcare I would say the challenges around making sure that the data is protected and safe they’re very similar.

I mean, as you can imagine in financial services there is quite a lot of regulation to make sure that there is privacy and there’s really good scaffolding around the use of that data.

So, maybe the unique challenge that I’ve been seeing presented by healthcare that might not exist as much in other industries is really the interoperability issue. So, it’s really related to the fact that we have not been able to get a data set that shows a continuum of care for a patient and while interoperability isn’t exactly perfect in other industries, in healthcare we’ve seen that to be a unique issue and specifically, we’ve been seeing it come up when we’re trying to understand population health management or trying to understand a more full view of the patient and how they consume healthcare services and really what their current state is in terms of what their needs are in healthcare whether they need to have prevention and other interventions.

And we have not been able to really get clean data, because it sits in different places and it sits in different systems that don’t speak to each other as much. I think that’s the biggest issue and I think maybe if I were to define a second issue that’s a really big challenge is really having the data be good quality and I think that that’s related to transparency as much as anything because a lot of times the patients, if they were able to see their data they would correct it, they would say, look, this does not reflect actually why I came to see the doctor today even though the doctor noted it as such.

And while that’s not necessarily the full answer allowing the patients to edit their data, it’s suggestive of the fact that the quality is a lot of times very low and there is a lot of kind of error involved in the information. And of course, the algorithms are only as good as the data that goes in.

So, that’s a high-level response. I’m not sure if that answers your question or do you want me to elaborate?

**Gilad J. Kuperman, MD, PhD, FACMI – Director Interoperability Informatics – New York Presbyterian Hospital**

No, that’s very helpful. I appreciate it. Thank you very much.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Okay, Lucia? I think you might be on mute.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

I’m just getting off mute. I have two questions, one for Ella, just to understand, when you are doing analysis for clients in healthcare or life sciences are the data sources that you’re drawing from what…like would be typical of healthcare like claims or EHR data? Or are you bringing in data, as we talked about on Friday that is about health but is from Non-HIPAA sources? That’s question one.

**Ella Mihov – Director, Healthcare Team - Ayasdi**

Sure.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

And then question two is, could you talk a little bit about what…would your learnings be better or more informative if you weren’t working with de-identified data sets? That’s the second question.

**Ella Mihov – Director, Healthcare Team - Ayasdi**

Well, both great questions. So, in terms of the first one, in terms of just thinking about kind of the data that we use, we believe that, given the state of the industry and thinking about kind of the adoption of analytics, it’s enough for us as a huge accomplishment to even really understand EMR data and understand claims data. So, we’re really focused on just getting that right.

And a lot of time there is unique opportunities that are presented in combining EMR and claims data. So, there are things that are not available in EMR data that exist in claims data, such as a little bit more about the continuum of the patient’s journey, as well as, there is information in claims data such as whether a pill was actually purchased after it was prescribed that do not exist in the EMR data. So, we do believe that that’s really where we want to stay for the time being.

We understand that there is a tremendous amount of opportunity in patient generated data and things that come from medical devices within a hospital. And we are starting to get interest for that but what we found is that industry is really not there yet and massively investing in those types of questions that come out of…maybe come out of patient generated data as well as some of the more exploratory questions that come out of taking even wearable data, things like that.

We believe that really the majority, right now, the challenge that we want to tackle which where the value is, is around just taking clinical and financial claims data. So, hopefully that answers your question. And we do work with the providers and the payers own private data, so we do not take, yet, at least, other sources to fuse them together.

So, in terms of your second question, if the data was not de-identified, I think the main things to

me, that comes up is the richness around that specific person and maybe a little bit more about kind of their own perspectives and information related to more of kind of the mental state of the individual, whether they have other issues going on that are more on the personal side which might be available if the data specifically had an identity related to each patient ID. But at the same time, we’re really not focusing on that, yet because we feel like there’s enough of really tremendous opportunity with just de-identified data, today.

But I’d be very curious to know what other people have or what perspective other people have on this topic and whether there is a movement to allow for non-de-identified data.

**Kald Abdallah, MD, PhD – Chief Project Data Sphere Officer – Project Data Sphere, LLC**

Hi, Kald here. Just a comment on the last comment you made. I really do…I think we have from the time we launched in a just limited number of data sets we had was about 18 we have now and from a universe of probably around 7000 or 8000 clinical trials that we hope to aggregate and work on we already have plenty to do, it’s already very busy with many different researchers and many different perspectives coming out from things that we didn’t anticipate when we launched six months ago.

So, we’re learning a lot from de-identified data and we believe there is plenty to do. Of course, in the future if there are discussions about other, how to make that data more complete may be could be more useful. I don’t know. I wouldn’t expect really too much but I agree with you we are already very busy with the data we already have and this is…at the same time exciting but also challenging.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Great, thank you very much. Do we have other questions from any of our Workgroup members or our Liaisons from the Federal Government? Okay, terrific. Well, I think we can go ahead and thank our panelists Ella and Kald it was incredibly helpful. We will be digesting the material we get from this hearing for, you know, several weeks and well into the next year and I hope you both would be willing for us to throw questions your way if more things come up as we, you know, start to deliberate on these issues. It would be great to continue to have your input on some of this.

**Kald Abdallah, MD, PhD – Chief Project Data Sphere Officer – Project Data Sphere, LLC**

Sure.

**Ella Mihov – Director, Healthcare Team - Ayasdi**

I would be happy to contribute, thank you.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Oh, great.

**Kald Abdallah, MD, PhD – Chief Project Data Sphere Officer – Project Data Sphere, LLC**

Yes, for sure, any time.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Oh, great, terrific. All right, well, I’m looking at the clock, we’re a little bit ahead of schedule but we’re also due for a break. So, I’m going to take us into a break and ask for folks to come back, go ahead and take…since we have gone without one, we’ll go ahead and take…let’s go ahead and take a 15 minute break just to stay on the 5 minute increments which means if people can be sure to be back at 3:10 we’ll start our next panel a little bit early and we’ll go from there.

Okay, I have 3:10 on my clock, on my computer. Stan are you…

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

I am ready and willing to go.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

All right I think we...

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

So, let’s go on with our next panel.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

I was going to say it looks like both of our panelists are on from…

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

Yes, Paul and Josh are you on?

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

Yeah, hi, this is Paul, I’m here.

**Josh Gray, MBA - Vice President, athenaResearch – athenahealth**

And this is Josh, I’m here as well.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

That’s great, well, let’s get going with this next panel. We’re excited to welcome Paul Wallace who is going to be our first speaker, Paul is the Chief Medical Officer and Senior Vice President for Clinical Translation at Optum Labs. Paul, take it away.

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

Great, thanks very much and appreciate the chance to spend some time with the Working Group and to share the work that we’ve been doing at Optum Labs along with our Co-Founder, Mayo Clinic, and several other partners to develop a research and innovation ecosystem. If I could go to the next slide.

Our approach at Optum Labs has been to create an overall set of processes that really is a learning healthcare system and looking in the sort of lower left-hand portion right next to researchers we need to ensure that the topics that researchers are investigating are important at the delivery system can align.

Discovery is designed to include multiple different inputs and a diverse research data that we’ll talk about in a second but also designed with the end in mind to include translation and subsequent adaptation to produce health outcomes and a variety of different illustrative system settings. If we could go to the next slide.

A key asset within Optum Labs is the database. The Optum Labs data warehouse includes about 7.7 terabytes of de-identified data that are derived from administrative claims for over 100 million individuals collected over 20 years, clinical data from both structured and unstructured fields of electronic health records for over 25 million patients, plus consumer data on approximately 30 million Americans.

The de-identified data is linked across data sets at the individual level using the hashing techniques which were described in the Health Affairs paper and other materials I shared. After confirmation of the appropriateness of submitted study protocols data is provided to investigators through a secure enclave as one of several de-identified views certified as HIPAA compliant. Researchers are not allowed to download any patient level data from the enclave further reducing the risk of re-identification. If I could go to the next slide.

The premise of Optum Labs in addition to data is to combine the insights of multiple partners. So our partners are actually shown here. Our founding partner was Mayo Clinic and along with Mayo Clinic a key partner has been AARP. We also though include the American Medical Group Association which includes about a third of American physicians and touches approximately 100 million Americans in care delivery. The partners are drawn from academia, care delivery, industry, technology and patient and consumer interest. If I could go to the next slide.

We now have approximately 130 research protocols that are under active investigation. And while initially many of them were developed within Mayo as our sort of founding partner it now involves all of our partners in some form of discovery.

And transitioning to the next slide we have systematically been designing studies to include those who would translate at the earliest processes of initial protocol review and research project design. Our expectation is that around 30 to 50% of the studies that are being actively done will be available and appropriate for expeditious translation. If we could go to the next slide.

We’ve also found this data asset has been both attractive and supportive of looking at complex larger portfolios of problems such as heart failure, Alzheimer’s disease, complex comorbidity, diabetes and also we’re in the process of creating a…with the National Quality Forum, a performance measure incubator.

The mix of methods that have been used range from observational studies and machine learning and the outputs range for models to novel registry specification, performance measures and decision-support and if we can just go to the last slide.

These were several policy implications that we had noted in the original Health Affairs paper that obviously hasn’t been fully solved, but I think probably the key is noted in italics that there is substantial potential for the safe and innovative use of de-identified data. I think that creativity allows one to work through a variety of challenges although there also are needs to create new observational and methodological approaches.

A key issue is going to be opportunities for systematically coordinating uses of de-identified techniques with subsequent use of HPI, one example of that would be registry specifications. There is also a great deal of opportunity, I think you heard about earlier, for how we can use machine learning.

Governance is complex but is being addressed and key issues are going to be, I think, as this continuous to evolve, informing and engaging Institutional Research Boards also as partners to think both about methods and the data sources involved, refining the relationship between QI and research, and also thinking about guidance and observational methods.

Sustainability is going to be big challenge and probably the last piece would be thinking about how in the mix between private and public funding can support the whole balance of research translation and commercialization. So, thanks, very much.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

Wow, that was to the second, that was wonderful. Thank you very much, Paul, that was great and we will have plenty of questions for you in just a minute.

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

Okay.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

Let’s ask Josh Gray the Vice President of athenahealth, Josh if you would care to give your presentation, please?

**Josh Gray, MBA - Vice President, athenaResearch – athenahealth**

Thanks, Stan, really appreciate the opportunity to talk to you today. I’d like to just give you a little bit of a sense about some of the things that we’re doing as a cloud-based provider to support learning health systems both across our client base and beyond.

So, by way background athenahealth is a cloud-based software and services company with 59,000 healthcare provider clients around the country. We provide doctors with electronic health records, practice management and care coordination services.

We’re a little different, our technology is cloud-based, it is a single instance software platform and as a result all of our clients use the same version of the same software. The data that they enter is immediately aggregated into databases that we host and that gives near real-time visibility into medical practice patterns. We use that information to help our clients improve their performance.

Our approach is actually fundamentally different if you compare us with conventional EHR companies that sell software to individual health systems. You know thinking about the data as from kind of on premises vendors is locked up in isolated pockets around the country and it can be accessed but it’s challenging to give researchers access to that data at scale across health systems.

Our clients, again because it is a single instance software structure, are effectively part of the dynamic learning system where data flows relatively freely. Most of the doctors that we serve are community physicians and it turns out that their nationally representative of community doctors in US as a whole and what that means is that we essentially have access to a near real-time digital snapshot of how community medicine is practiced around the country and using this data we can shed light on a wide range of questions regarding what works in healthcare. Let me just give you a couple of examples to give you some color to that statement.

So, the first application that I wanted to talk about is dynamic guidelines compliance tracking. So, at this point we have almost 200 clinical guidelines based on specialty society standards programed into our EHR. We’ve got guidelines for hypertension, diabetes, as many of the sort of standard conditions as well as some less common conditions as well.

With a couple mouse clicks doctors can activate a guideline, for example a primary care practitioner could find out how many diabetics he has and of those how many had a recent hemoglobin HbA1c test under 7 on file. She could compare her performance with physicians in her practice, in her geography and across athena.

So, in terms of learning health system principles this helps our clients learn where they could do better in complying with best practice and complying with clinical knowledge. With another couple of mouse clicks physicians can have e-mails or texts sent to all of the patients that they have that are out of compliance with a particular guideline to bring them in for care.

Example number two is disease surveillance, every week the 20,000 or so primary care providers that we serve see about a million patients. We monitor those visits for diagnoses of influenza-like illness and what we found is that our results sync up really well with this CDC’s flu figures, but, again, because we’re cloud-based we can report figures with a 24 hour delay.

We are currently providing a de-identified data stream ILI to epidemiologists at Harvard School of Public Health, Children’s Hospital Boston and Health Map who use the data to refine their prediction models. We also provide flu feeds to several public health departments without charge and they’re actually looking for other partners to support as well.

Last example that I’ll leave with you is a project called ACA view for the Affordable Care Act, which is a partnership between us and the Robert Wood Johnson Foundation, where we’re tracking the impact of the ACA on community doctors.

We have a sentinel group of about 15,000 providers and we’re taking meticulous measurements on how many patients they’re seeing and the health status of their patients, how much patients are paying out-of-pocket for their care and so forth. It often takes years from when a policy is introduced to when it is effects are measured, we’re trying to compress that time to a matter of weeks or months.

In short, we think that in the long-term electronic health record data will gradually move to the cloud because it’s a better technical model. As it does we think some of the barriers that have kept the data somewhat bottled up will begin to fall away. It will be easier to work with data at scale across providers. It will be easier to narrow the gap between clinical practice and clinical research to the benefit of patients. So, thanks.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

Fantastic, thanks very much for your presentation as well, also incredibly on time. But we do I’m sure have lots of questions cueing up. I don’t see hands raised at the moment, but, so again, I will take the prerogative to ask a couple, at least one here.

Both of you clearly are in the cutting edge of data aggregation, data analytics and real-time, you know, kind of data use and we’re very interested to know if you’ve got ideas or thoughts about how a regulatory or a legal system or a guidance system or anything else that could keep pace with how quickly you are moving on in your technology areas?

So the idea that you have to wait, you know, six months for regulations to be developed publicly and come to fruition and finally passed in year in total when the system keeps moving forward, you know, does informal guidance play an important part or could it or self-regulatory practices within areas? Do either of those have things or your own thoughts?

**Josh Gray, MBA - Vice President, athenaResearch – athenahealth**

I will, it’s Josh, I’ll take a cut at that if you like. So, you know, I think we tend be fairly risk-averse, you know, pretty much all of the analytics that we do are…as I think is the case with Optum, is done on a de-identified…only with de-identified data elements and data structures. So, you know, it’s obviously an incredibly important principle to adhere to.

In terms of what would make things easier I do think informal guidance is very helpful. Part of the areas that we struggle in is, you know, depending on the analysis that you’re talking about, you know, there can be a fair amount of state-by-state variation in how say HIPAA regulations are or I should say privacy related regulations are defined and it takes us in an awful lot of time to sift through all that material and, you know, make corrections or modifications.

Anytime there’s a major refinement of HIPAA we really have to, you know, very closely scrutinize all of our policies and procedures about handling data and conducting analytics and interacting with clients in their trading partners and so forth.

So, you know, it’s a critical issue. It does take up a lot of time. I think consistency across states and, you know, obviously it’s easy to say, hard to do, but just spelling the regulations out in as crystal clear a fashion as possible all would be extremely helpful.

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

Yeah, I guess what I would add to that is that we see privacy protection as a…and safe and appropriate data use as a combination of both technologies but also the other like research review processes, the appropriate training and credentialing of researchers, the engagement of the researchers sponsoring organization in both getting and validating the appropriate use by their investigators.

So, it’s recognizing that it…as you know well, it’s a multifaceted process of both technology and the social and organizational systems that support them. And I think I’d also reinforce what Josh said that because of the complexity of this it’s important to have the earliest possible signal about where changes may be coming from and ideally to be part of the process it helps to identify where those changes are so that we can do the appropriate adaptation of our overall approach to, you know, preserve confidence and trust in the overall approach.

And maybe the third point where I’d also just agree is that we’re pretty conservative about this, about, you know, being well within the bounds because, you know, this is…information is our business and we want to be a trusted source and an appropriate source for information but at the same time we want to not carry when there’s the opportunity to move forward so knowing when there’s change coming and being able to fully incorporate it so we don’t have any lost cycles is important to us.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

That’s great. I have a Workgroup member, David McCallie?

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Yes, thanks, I’ll start with Paul. If you could go into just a little bit more detail about the data enclaves that you mentioned and what that actually means and in particular do you have rules on how the data should not be used, for example do you prohibit any kind of attempt at re-identification? You went through that material incredibly efficiently but I didn’t follow every bit of it and if you could just elaborate a little bit on that?

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

Sure, I’m sorry if I went through it too rapidly too. I think that we provide the appropriate de-identified view to the investigator in an enclave and a thin client. Now we also work with the investigator during the research proposal process to determine which of the several available de-identified views would be the appropriate one for the research they’re pursuing.

There may be situations where the investigator would wish to add in other data but before we would allow that we will also need to recertify that after the addition of that data we preserved the appropriate level of de-identification to be consistent with HIPAA. And we would not allow addition of other data.

We also don’t allow removal of individual level data from the enclave or sandbox just for that same reason so that it can’t be combined with other data sets outside of the controlled environment. Did that answer your question?

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Yeah that was very helpful. Let me just make sure I understand you said a thin client, does that mean that the individual researchers don’t have a copy of the data in their own database they can only use tools that you give them to sift through data?

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

Right.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Is that…

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

Well, the data never leaves actually our environment although we can obviously place it on their workstation wherever they are in the US. We also though work with them to figure out what are the tools that they would need to have present, we supply certain things like…and a variety of things but do they have additional analytic packages we’ll work with them so that they’re a component of the enclave or the sandbox. And we, you know, dot those I’s and cross those T’s during the statement of work process that’s preliminary to our actually setting up the enclave for them to do their research.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Okay, and so they don’t have ability for example to join it against a local database unbeknownst to you? That’s…

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

No and that would be…

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Not possible?

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

That’s explicitly…that’s explicitly excluded in the statement of work. It’s part of…in our licensing agreements with the organizations and it’s something we monitor also.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Are the researchers all IRB approved or is that not required since its de-identified data?

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

Different researchers have taken different approaches but we have researchers who are using it who have felt that because of the de-identified nature it didn’t need to go through their IRB. But we defer to the organization for them to understand what’s appropriate in their research environment. We don’t require local IRB approval before we provide access to the data.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Thanks, that’s very helpful.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

Great and I have Lucia and Deven as well. Lucia Savage?

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Thank you, Stan. I have two questions for both Paul and Josh. One is like some prior speakers it seems like really you’re just…you have plenty to do right now with the data that we would just call traditional healthcare data.

But I was wondering, you know, pull out your crystal ball, how long would it be before, for your your business models or your, you know, planning would you be wanting to bring in this data about health from non-healthcare environments like fitness or whatever, we’ve been talking a lot about that, that’s question one.

Question two is specifically for Paul and I’m going to go there first which is I understand you’re using sort of this combination of clinical data and claims data and I know that what the researcher has access to is de-identified but can you talk a little bit about when the data arrives in your custody or in your enclave is it already de-identified as a prior speaker suggested that the suppliers de-identify it, are you de-identifying it and if you are, to make the data work together effectively for research do you need it to arrive in an identifiable state so you can match or can you make it work without having individual identifiers for matching purposes?

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

Sure, well, let me…so as far as the site where the de-identification takes place, the data donors remove the direct identifier. But they do it in…we send them a hashing algorithm along with a specific salt so that the PHI is systematically de-identified and we send the same salting, the same salt and hashing algorithm to all of the data donors. So the PHI will be systematically and consistently de-identified in the same manner.

So once we receive the de-identified data we can match on the hashed PHI fields. So we can bring together, so, like, you know, Paul Wallace would become XYZ but I’d be XYZ from all of the data donors. We can then bring together all of the XYZs and before we provide that data out to an investigator we actually hash it again so that they couldn’t work backwards.

**Claudia Williams, MS – Senior Health & Health IT Advisor – Office of Science & Technology Policy – White House**

Hey, Paul, this is Claudia, at OSTP, does that mean that there is some kind of commonly held set of demographic information that permits that hash across entities and if so who holds that?

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

Well, there is a…the hash that we use is actually one of the NST hashes. You know it’s a NST hash and then so it’s a common…it’s a public source hashing algorithm and the trick is what we supply is the salt so the people end up in the same place.

**Claudia Williams, MS – Senior Health & Health IT Advisor – Office of Science & Technology Policy – White House**

I guess I’m wondering more about when you’re trying to match people across different databases obviously the matching of those people becomes very tricky and often requires some kind of normalization of the demographics.

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

Right, well so we also then we can…our algorithm we wouldn’t match just on name, the hash name, we would also match on other hashed identifiers. So, we, you know, just to back up, you know, like Bill Crown and William Crown wouldn’t match in terms of just name but when you actually add in the other fields that we use in that algorithm we can have a high confidence of match. But again using…

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

So…

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

This is using the hash data that we would be doing the match on.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

So, even given the same salt and as long as the same data goes through the salt then you get the same encrypted identifier on the back end that you can then match.

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

Right, because, I mean Paul Wallace will come out XYZ…

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

Right, right.

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

Using the same salt and the same algorithm so we can match an XYZ plus my other hashed identifiers.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**   
Right.

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

Did that answer your question, Claudia?

**Claudia Williams, MS – Senior Health & Health IT Advisor – Office of Science & Technology Policy – White House**

Yeah, thanks.

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

Okay.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

This is David, let me, can I…

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Yes…

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Oh, go ahead.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

David, before you go…I don’t mind going down this list, I don’t mind going rat hole I just want to make sure I get a chance to get back to my other question.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Yeah, okay.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

So, give me chance and then we’ll turn it back over to David.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

No mine is a technical detail I can…I mean, let’s go back to your main question.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Okay.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

I’m into hash…

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

We do have some other participants too though Lucia so we need to work through things.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Yeah, so my second question was about at what point in the future, down the road do you think you’ll be wanting to apply all this amazing technology that you guys have to Non-HIPAA governed sources of data and that’s for both Josh and Paul and hopefully they can just pick a year out of a hat and it will be short.

**Josh Gray, MBA - Vice President, athenaResearch – athenahealth**

Well, this is Josh, I’ll jump in. So, you know, we’re concerned not just about legal compliance but also about how our activities are perceived, you know, kind of generally but across our customer base as well. And so I feel…you know, I guess I’d say two things.

One is that even without these data streams that you’re describing I feel like we have a solid decades worth of work with what we have. It really is kind of a treasure trove of data that we’re only just beginning to scratch the surface of. I would love to be folding in tracking data and so forth, but I think we are risk averse to the extent that we need a very safe and well-articulated roadmap before we did that.

I’ll just…really quickly one area that we are very eager to get going on is to actually use a cloud-based infrastructure to try to identify doctors that would be suitable to particular clinical trials and to really kind of reengineer the technology to make it very dramatically simpler for physicians, and general community physicians in particular, to participate in trials. It’s something that there’s an objective crying need for. We’re just beginning to do the, kind of the regulatory assessment of some of the issues there. But I would flag that and that’s something we’d love to get going on within the next year or two.

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

And this is Paul, we’ll in 2015 we’ll be bringing in other data and I expect it will be in…similarly it will be use case and problem formulation driven but we have problem formulations in the queue where we would…where the analysis would benefit from including things like aspects of consumer data. We’re also likely to initiate some work to bring in some patient generated outcomes.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

Great. David, did you say you had a question?

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

If everybody else has gotten their questions. I was going to go a little deeper on the hash question but it was really technical.

**Linda Kloss, RHIA, CAE, FAHIMA - President at Kloss Strategic Advisors, Ltd.**

This is…

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

Linda Kloss I think has a question.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Yeah.

**Linda Kloss, RHIA, CAE, FAHIMA - President at Kloss Strategic Advisors, Ltd.**

Yes, thank you. This is for either of you, but primarily Paul, I understand that you had experience with combing clinical, financial with some socioeconomic information. Are there articulated sort of guidance that you’ve developed with regard to, you know, cell size and other kind of results of the mosaic that’s actually bringing these data sets together that are developing as you gain experience with working with other kinds of data? And the same question to Josh. It seems to me that there is a wealth of lessons being learned that could help inform the policy environment.

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

Well, I think I’m not sure I’m the right person to articulate the learnings down to the, you know, the technical specification, but to your point I think that each time one brings in an additional data source even if they are similar one learns both the technical and social issues in bringing together particularly disparate types of data broaden that.

So, you know, we’re in the process of bringing together the claims data and the clinical data and I expect that we will have and, you know, would be glad to engage in workshops and other things to think about what actually is involved in bringing these things together.

I don’t want to hedge your question but I also don’t want to misstate, you know, an important technical learning that might become better from a technologist than a chief medical officer.

**Linda Kloss, RHIA, CAE, FAHIMA - President at Kloss Strategic Advisors, Ltd.**

Well, it seems like when we are melding in geo data and socioeconomic we kind of layer on new kinds of questions or concerns with privacy and security and these are the kind of leading edge issues that I think this Workgroup needs to think about.

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

Yeah, and, you know, we learn a lot every time we do this too and working with our consultants. So we spent a great deal of time whenever we have one of these, you know, working with our de-identification consultants to do the due diligence and work through all of the permutations about something I think that’s as much as…one of the challenges is that those are, you know, while relatively rare individuals, and we’ve nationally placed a lot of burden on a very few people as this area is going to expand.

So I think cloning is obviously not an option but I think we need to think about how we can, you know, ramp up the capacity for that kind of expertise to the extent that that’s going to be, you know, an appropriate way for us to create these research ready views.

What I can tell you is that the demand, the supply and demand thing…but as we grow this capability I expect the demand will grow very fast.

**Linda Kloss, RHIA, CAE, FAHIMA - President at Kloss Strategic Advisors, Ltd.**

Thank you.

**Josh Gray, MBA - Vice President, athenaResearch – athenahealth**

Yeah and it’s Josh, just to jump in on this topic and I hope this is responsive to your…at least the spirit of your question. So, you know, at the end of 2013 we had pretty comprehensive claims and clinical feeds on about 12 million patients that had received care in that year. And even without going to, you know, other data sources to import more socioeconomic data on the particular individuals, you know, we know what their insurance is, we know where they live and so one can infer at least from socioeconomic characteristics to folks and even without kind of looking at other data sources we’re able to track, you know, for example how much patients have to pay for their care over time.

You know for example this year for newly insured patients how much do newly insured patients have to pay for their care, we’ve not yet linked that to health outcomes but we’re working hard to figure out a way to at least move in that direction and so, you know, I think as I tried to get out a little bit in the opening comments, you know, having…being able to bring together a clinical and claims feed knowing where…you know, how patients are insured actually I think does give you pretty good…a pretty good window onto policy issues.

And I think the ACA, in particular, is a great and actually very important test case for that and that’s why some of the work we’ve been doing in partnership with the Robert Wood Johnson Foundation has gotten off to an exciting start but I think it has a huge amount of potential the next year or two.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

Great, thank you.

**Linda Kloss, RHIA, CAE, FAHIMA - President at Kloss Strategic Advisors, Ltd.**

Thank you.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

Deven?

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

So, I…you know, I had two question topics on my list, one was the hash algorithm but I’m going to hold off on that one because I know David has a follow-up on that. I wanted to get to the sustainability issues that, Paul, you raised on your slides although I invite both of you to address it.

How does the work of Optum Labs for example get funded? The 130 research projects I think you said. Do the people who bring the questions to you that they want to use your database to address, are they sort of required to bring a funding source to support that or how does it generally work and what does that mean for other types of models where were we want to encourage this type of data analytics?

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

Well, I guess from our experience I suspect it will take a portfolio or the same way that we have a portfolio of members they’ll have different ways that they will support. So some members support by providing data, some support by providing funding, some support by providing collaborators to participate in research being funded by others.

And then we also have a fair number people that are doing grant supported research where the data that we can provide is the substrate of their research. And then we also have a cost recovery fee for the actual cost for providing the data.

So, you know, I think the business models for these enterprises are probably necessarily going to have to tap multiple sources of support and, you know, I think that basically trying to do it in…and also, you know, sort of how long it takes to set it up to where you become actually sustainable and self-sufficient. But our expectation is that this takes a couple years but again from those different mixes of support.

**Josh Gray, MBA - Vice President, athenaResearch – athenahealth**

And just to…it’s Josh, just to add my two cents to Paul, I mean, I think our, you know, activities in this domain we don’t come close to covering our costs. I think we are viewing this as a way to, you know, give back. We think we have a really interesting view on what’s happening across the delivery system that’s somewhat unique and we’re happy to provide data to researchers to publish where we can and so forth.

To this point we have just done two things. We’ve received some foundation funding. We’ve received some very, you know, kind of small levels of support from academics that we’ve supported concretely, but you’re right, if one were to scale this out pretty dramatically, you know, we, as Paul says, we’d probably need to expand the funding sources to a considerable extent.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

Okay, I’ve got David McCallie and then Lucia I see your hand up too. David you had a follow up question?

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Yeah, I’m going to ask a new question I think instead of the detailed question I had in mind. And I don’t think Paul you answered it but I’ll ask it just in case.

If something turns up in the researchers use of the de-identified data that requires or could require actual re-identification of the patient either because there was something that patient really ought to know or perhaps they could be a candidate to be recruited into an interesting trial that might benefit them or whatever the reason. Do you have the ability to do that? Is that a permitted process in your system, re-identification?

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

No, the hashing algorithm is a one way hash. That doesn’t mean that we couldn’t let…if there was something, you know, I can imagine all kinds of things, but the hash is a one-way hash. So, we wouldn’t be able to break the code and tell you who the individual was.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Okay. So you don’t allow it even though technically you could if you save the salts but…

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

The…

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

It’s not a normal use case, that was my real question.

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

Right.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Thanks.

**Linda Kloss, RHIA, CAE, FAHIMA - President at Kloss Strategic Advisors, Ltd.**

Could you refer it back to the provider?

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

Yes.

**Linda Kloss, RHIA, CAE, FAHIMA - President at Kloss Strategic Advisors, Ltd.**

The originator would do that?

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

Yes.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Oh, you do allow that so that’s really what I was looking for.

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

Well, I mean, I guess I would…you know, I think that you posited a fairly…it would probably be a relatively extreme finding.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Yeah.

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

And, you know, we’d be assuming that this would be an extreme finding that would become evident with sort of later observational data analysis that wasn’t apparent during the course of care. But, I mean, I can imagine where that might happen but we have not created a mechanism for systematic re-identification.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Okay, thanks.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

Lucia?

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Yeah, so this is a question for Paul in terms of these other data sources that you want to bring in starting just in a couple weeks I guess, could you talk as best you know and I know you’re not a lawyer, but could you talk about what are the ways in which the people reflected in that data understand that it’s going to be given to Optum Labs for this research or is it not relevant because it’s solicited from consumers really and then de-identified according to whatever those standards are? Like, how do you get to sort of the fair information practices part of that? We all know how it works in HIPAA.

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

Well, I mean, I think that’s the process that we have to engage in to make sure that we’ve checked off all of that, you know, and it depends on what the use case was for which the data was actually collected.

You know there may very well be patient generated outcomes that were collected with, you know, either some degree of consent or some degree of understanding or collected, you know, in an appropriate use. So, I think it’s use case dependent. So, I’m not sure I could give a blanket statement to how that will play out.

But part of what we would do with any source of data that we would bring in would be to ensure that it doesn’t, you know, compromise our core ability to provide trusted data.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

So, Stan, can I just ask a follow-up question?

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

Sure.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

So, some of our earlier dialogue today was about, you know, as we get to these additional sources of data and we sort of migrate…the data we want to use migrates out of the HIPAA world, what can we, you know, take from HIPAA or what should we not take from HIPAA to apply in that and Deven in her witness hat not her chair hat sort of had posited, you know, can we have a situation where fair information practices are clearly applicable to all data that concerns individuals.

And I guess I wanted to ask you and Josh, you’re sort of implying that we need a lot more clarity. Is standardization, in terms of the rule structure, is standardization within the scope of what you mean by clarity like so that you don’t have to worry about the domain the data came from but the basic way you

would handle it and the rules that adhere to it and what the individuals interest in it are the same no matter what or have you thought about that at all?

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

Well, we’ve thought about it a lot. I think, that I’m not sure I would say that we have thought about it to the point where we could articulate clear policy recommendations but I think that’s been partly because, you know, we’re one of many stakeholders in this and we can contribute to policy.

I think, you know, going back to, you know, I guess what we said at the very beginning about being conservative in this our view is that we want to add in data that will allow us to compliment and extend the ability to do the research but we don’t want to violate again the core concept that’s embodied in

HIPAA and how that translates operationally I think is what we’re going to have to work through on each one of these different use cases.

I guess the other part about that would be I think where there’s a huge opportunity from government is to not have everybody doing all of that independently but to create, you know, shared understanding and learning as different people are working through different aspects of this.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

Okay.

**Josh Gray, MBA - Vice President, athenaResearch – athenahealth**

And it’s Josh I’d just add I think it’s fine to have different, you know, guidance and principles for different modalities it’s just, you know, leaving as little as possible open to interpretation so that is the only plug I guess I would personally make.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

But just to follow-up…

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

The other…

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Is that one of the tensions, Josh, it’s going to be right, the more specific you are the faster it becomes fail.

**Josh Gray, MBA - Vice President, athenaResearch – athenahealth**

Yeah.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Right there’s a tension there and we have to really be careful because that’s kind of where we found ourselves in a place of rapid technological advance where it’s very hard to keep the rules up-to-date in the specificity.

**Josh Gray, MBA - Vice President, athenaResearch – athenahealth**

I see, yes.

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

I mean, I guess the other would be, you know, what are the…there is a specification remedy, there’s also a remedy that looks at nondiscrimination and I mean, I think that, you know, in GINA I guess is an example of that where, you know, there is a compliment between how we on one hand seek to protect and on the other ensure nondiscrimination. So, I think those two probably are interrelated also going forward.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

Let me pause and just ask if there are comments from the Workgroup or government members on the phone? Okay, Deven, you had your hand up.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yeah, I did sort of along the thread that we’ve been talking about, about, you know, sort of how we keep regulation and policy sort of up-to-date with where developments are going. Is there a role…do we rely too much on government to set the standards here? Is there some sort of mix of, you know, sort of where the private sector could go with keeping up, you know, some of the standards that may be a little bit more sensitive to the need for flexibility for technological innovation while, you know, relying on government for sort of more hard guardrails that we might not need to change as frequently and if so, what are some sort of trusted private sector bodies that we could use for that assuming that we could get agreement that some sort of public/private approach to all of this is the way to go?

**Josh Gray, MBA - Vice President, athenaResearch – athenahealth**

I mean, I love the…I appreciate the spirit behind that and the principle of providing broad guideposts allowing some private sector flexibility. I wish I were knowledgeable about private sector entities that would be helpful but I love the principle.

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

I guess I agree with that too in the sense that I think that, you know, government has an important role in setting the clear boundaries but I think it also has a role to set boundaries that allow flexibility within those boundaries because that’s where innovation is going come.

So, defining, you know, sort of the floor is going to be critical also ensuring that there’s actually discussion around how to, you know, evolve the understanding of I think overall government that I think the degree to which can build on examples with other standard-setting groups, you know, from HL7 to SNOMED I think is going to be important to try to make this continuing to move forward.

And I think it’s just…the questions have illustrated just the complexity that you’re more aware of than we are probably about what’s going to be challenging as we, you know, leave these domains that we understand reasonably well and start bringing in those kinds of data.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yeah, yeah, I don’t…I mean, I appreciate the responses for both of you. I think it’s always a challenge when you think about public/private sort of cooperative frameworks to sort of thinking who is the trusted entity on the private side in terms of, you know, somebody who is knowledgeable about the industry demands and the need to leave room for innovation but that, you know, the consumers and the policymakers are going to similarly trust.

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

Well, I think, you know, HIPAA is a great example with a sort of clear boundary around, you know, around removing identifiers but also the flexibility for the expert view and I think that’s a both “and” which recognized the importance of…you know, it clearly made the burden on the user to demonstrate that they have been appropriate in faith but it also created the opportunity for the user to do that.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Right.

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

So, I think that that’s a good model to think about how we can, you know, have a clearly bounded state but have degrees of freedom within that.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Thanks.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

Great. We probably have time for another question if there’s anybody. I don’t see any other hands raised. Is there anybody on the phone?

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Stan, this is Lucia, I’d like to do a follow-up question for Paul and Josh if there is time based on our Friday’s session?

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

Yes, go ahead.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

So, Friday afternoon we had this pretty interesting discussion about whether the HIPAA Safe Harbor, what are you…whether it was time to kind of revisit the Safe Harbor not that there would not be a Safe

Harbor because there was a policy need to have kind of something that people could implement easily but maybe what the Safe Harbor consists of needs to evolve a little bit as the technology has evolved. I don’t know if you guys had a chance to listen to that you’re both probably pretty busy but that’s the gist of the conversation.

I wondered if you have any thoughts about as we move forward and we’re trying to get more information but continuing to protect the privacy appropriately how do we make it easy, it kind of goes to the sustainability issue that Deven raised earlier.

So, do we modify the Safe Harbor, do we throw it out the window and have everyone use a statistical de-identifier certifier, what do we do to, you know, preserve the privacy but generate the information?

**Josh Gray, MBA - Vice President, athenaResearch – athenahealth**

So, I, it’s Josh I have to confess I’ve not yet had the opportunity to read through the Friday proceedings but I’m looking forward to it. We use expert determination. We get a set of recommendations. We, you know, never…how can I say this, we’re always even more…as conservative or more conservative as the outside reviewer suggests and I think that works pretty well.

You know you need to make different trade-offs as I think Paul was intimating earlier depending on the needs of the researcher and the inherent requirements of the particular project but we think it’s a framework that’s demanding and time-consuming but it is working for us.

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

I guess the only other comment I’d make is that I guess it was to what I was saying before that as we have more and more experience with the expert method it may actually lend itself in certain use cases to being done more efficiently even algorithmically.

And to me it’s an information science challenge that people are much better prepared than I but where one could begin to look at value of information in different settings and look at whether there is the ability to balance on one hand sort of clear-cut regulation in the middle where we rely on experts to give us degrees of freedom but there might be another layer where we can actually mimic or replace what the de-identification experts are doing now, you know, as the patterns and the ability to create these de-identified views evolved.

That’s a little bit, you know, wishful thinking perhaps, but I think there is some precedent for how we’ve been able to take experts systems in the past, automate them to some degree and the other part about that is it frees up the experts to have to help us at the leading edge.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

This is David, just to comment on that. It would still depend on your ability to enforce the user of the data as being unable to join it to data that hadn’t been anticipated by the expert. Right?

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

Yes.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

So, you know, the expert can anonymize when he has a fixed space of known data elements but as soon as you allow joins or mosaicking to external data elements all bets are off.

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

Yeah and I think that may just be an important boundary for us to…

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Yeah.

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

You know there is sort of…it’s to recognize the importance but also the relative danger, speaking to you okay, that of the unsafe use of these…that we have to have certain boundaries. It’s like when we create cancer centers, why we create P3 labs and we credential people and we create certain technology protections for how people can access, you know, hazardous materials and I think on some level we have to recognize that these are not…these are relatively…these are at least risky if not dangerous materials and so we do need to handle with care.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

That’s great and that takes us to the top of the hour and Deven we are set to launch into your next session if we have our speakers on health big data concerns. And thank you very much to Paul and Josh, we up really appreciate your time.

**Josh Gray, MBA - Vice President, athenaResearch – athenahealth**

Thank you for the opportunity.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yeah.

**Paul Wallace, MD – Chief Medical Officer & Senior Vice President for Clinical Translation – Optum Labs**

Yeah, thanks, again.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Both of you were terrific, thank you, so much.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Yeah, thank you very much.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

All right, we are moving into our last panel of the day on concerns about health big data. Do we have Leslie Francis on the line? Leslie are you on mute? We don’t see her. How about Melissa Goldstein?

**Melissa M. Goldstein, JD – Associate Professor Department of Health Policy – George Washington University**

I am here.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

All right, do you mind going first?

**Melissa M. Goldstein, JD – Associate Professor Department of Health Policy – George Washington University**

Sure, I will go first.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

All right, let me give you a proper introduction.

**Melissa M. Goldstein, JD – Associate Professor Department of Health Policy – George Washington University**

Okay.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Melissa Goldstein is a Professor of Health Policy and Health Sciences at the George Washington University Medical Center here in Washington, DC. We will have more complete bios for all of our panelists up on line because there is a lot more to your biography than just that. But you are here to talk about bioethics and the public health law perspective, and we appreciate you joining us today. Do you have slides?

**Melissa M. Goldstein, JD – Associate Professor Department of Health Policy – George Washington University**

I do not have slides.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

That’s fine. I just want to make sure that we didn’t need to cue something up for you. So, we’re ready when you are.

**Melissa M. Goldstein, JD – Associate Professor Department of Health Policy – George Washington University**

All right, I am bucking the system with no slides.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

No problem, go ahead.

**Melissa M. Goldstein, JD – Associate Professor Department of Health Policy – George Washington University**

Well, first let me thank the members of the Workgroup for the opportunity to speak with you today. I’m aware that I am now the next to the last speaker on the last day of this hearing so will make my comments brief.

My expertise as Deven just mentioned is in bioethics and public health law and ethics, and my approach to the issues that I was asked to address, that is health big data concerns for individuals, reflects my training and work in both of these fields.

I believe that it is critically important for us to keep the underlying principles and lessons of these two fields in mind as we pursue the new opportunities that big data introduces to advance medicine, improve health care and support better public health.

As you know, the field of medicine is primarily concerned with the health of individuals whereas public health is primarily concerned with the health of the entire population. While medicine and the ethical issues that arise in the medical arena focus on the treatment and cure of individual patients, public health instead aims to understand and ameliorate the causes of disease and disability in a population.

The field of public health ethics is typically thought of as having a more humanitarian as opposed to individualistic focus and the major legal and ethical tension involved is often described as balancing individual and community concerns. Because there’s often overlap between the fields however, these important distinctions can sometimes be overstated.

Importantly, the underlying principles and moral considerations of both fields, bioethics and public health ethics, are quite similar. The list that I want to highlight now was compiled in an article that I will provide to the Workgroup that was written jointly by many well-known experts in the two fields. I also want to note the similarities between some of the principles on this list and those included in the fair information practice principles.

The first is producing benefits which we know as beneficence. The second, avoiding, preventing and removing harms what we call non-maleficent. Third, producing the maximum balance of benefits over harms and other costs often called utility. Fourth, distributing benefits and burdens fairly which we call distributive justice and ensuring public participation including the participation of affected parties which we call procedural justice.

Fifth, respecting autonomous choices and actions including liberty of action. Sixth, protecting privacy and confidentiality. Seventh, keeping promises and commitments which we know as loyalty or fidelity. Eight, disclosing information as well as speaking honestly and truthfully both often grouped underneath transparency. And finally, building and maintaining trust.

Finally, I would like to highlight in my remaining time a few of the arguments in a paper that I co-authored recently with Professor Frank Pasquale of the University of Maryland Law School for a workshop sponsored earlier this year by the American Association for the Advancement of Science and funded by the Robert Wood Johnson Foundation.

The paper is titled The Future of mHealth responding to a changing regulatory landscape and I will provide it as background material for the Workgroup as well as the article I referred to a moment ago. While the paper focuses on policy issues emerging in relation to mobile health technologies or mHealth, the background of our discussion is clearly health big data. In fact the White House Report had been published the month before the workshop.

We point out that the future of the field is likely to be shaped by increasing concern about finding the proper balance between fair data practices and innovation. And also note that most of the data produced by such technologies is not covered by HIPAA as referred to by Kirk earlier today.

We take the position in the paper that the policy conversation so far on mHealth has actually been quite narrow in focusing on consumer facing devices for relatively non-acute health issues but that mHealth technology in general merits a more nuance discussion in the future.

We outline the existing policy framework including recent actions by government agencies including the FDA, FCC and FTC. We then move on to consider emerging issues in this area including the possibility of government assuring baseline levels of quality in mHealth by delegating certification authority to third-parties, potentially requiring alteration of the ways in which data collectors maintain their databases and potential creation of a framework that focuses more on the use rather than the collection and analysis of data.

We conclude by urging policymakers, that is this Workgroup, as a first step to go beyond simple notions of privacy or innovation to address broader social consequences of health information collection, aggregation and use and to delve deeper into actual business and employment practices that rely upon such information.

Thank you again for allowing me to contribute to the conversation today and I look forward to your questions and comments.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Great, thank you very much Melissa. I understand we have Leslie Francis on the line. Leslie, are you there?

**Leslie P. Francis, JD, PhD – University of Utah School of Medicine – National Committee on Vital & Health Statistics**

Yes, I am.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Oh, great. Great to have you. Leslie is a Professor of Law and Philosophy at the University of Utah. Thank you so much Leslie for taking the time to be with us today. Leslie is an alum of our group so it’s really nice to have you back. Did you have slides that we need to tee up?

**Leslie P. Francis, JD, PhD – University of Utah School of Medicine – National Committee on Vital & Health Statistics**

I did send slides.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Okay, there they are, just say next slide when you need them turned.

**Leslie P. Francis, JD, PhD – University of Utah School of Medicine – National Committee on Vital & Health Statistics**

Okay, so if you’ve got my title slide it’s now time for next slide. I should say I’ve also recently, until December 1st, had the great pleasure of Co-Chairing the Subcommittee on Privacy, Confidentiality and Security of the National Committee on Vital and Health Statistics where I served with Linda Kloss who is now one of you.

In my five minutes I want to emphasize three themes, an overview of the risks when communities use big data, the work of NCVHS on a stewardship framework and a toolkit for community data use and several low-tech problems that I believe need more attention than they have received in some of the recent discussions. So, next slide. Could you go to the risks?

I should emphasize that there are two kinds of risks we’re talking about here, risks to individuals of harm from violation of their privacy and larger scale risks to the community about data availability and ongoing data use for health improvement.

Because I’m interested in figuring out how privacy protections can work in tandem to further appropriate data use I’m emphasizing the latter type of risk in my comments here. Others have testified about how information might affect individual’s employment, insurance status, access to financial services such as credit, subjection to discrimination, sense of identity or self-esteem. Those are some of the major individual risks.

I think there are three likely problems, in particular, that might lead to community unwariness and reluctance to share or use data. First, people in the community might be surprised to find out, who has information about them, what information they have and what the information is being used for.

Second, people might be suspicious about these same matters. Such suspicion might be the legacy of unwelcome surprise, of histories of injustice or of many other factors. Finally, either surprise or suspicion may lead to shut down, the refusal to share information or to allow information to be retained or used.

All of these factors were operative with respect to blood spots retained from newborn screening resulting in the destruction of immensely useful sets of samples and the data they contained in Texas and Minnesota. Not surprisingly, these kinds of concerns may be greatest among minority communities where there already may be issues about bias in data samples and the need for data.

So three years ago NCVHS, as a general committee, undertook a series of initiatives about community health data use. Next slide, please. Two in particular were undertaken by our subcommittee, first we developed a framework for data stewardship when communities use data to improve their health. To develop this framework we began with the background of FIPS from the 1973 HEW report on. I’ve highlighted that, the link to that report on my slide.

This survey that we conducted made clear what Solon Barocas and Helen Nissenbaum highlighted for you in their testimony on Friday that models of information protection were developed using anonymization or consent strategies, strategies that are outmoded in today’s world. For example they all provide protections for identifiable information but leave data without identifiers off the table.

I should say also that in developing our stewardship framework we had to extrapolate from FIPS to cover all situations of data use and in order to do this we heard testimony from a wide range of communities, data users and privacy advocates all of which is available on the NCVHS website.

We constructed a framework which we then used in our toolkit of eight elements of data stewardship, openness, transparency and choice, purpose specification, community engagement and participation, data quality and integrity, data security, accountability and de-identification.

There are many technical issues here. I want in closing, to highlight three of the lower tech areas that I think require more attention and this is…move to the last slide.

First, accountability, communities using data need to identify a go to person who is responsible for implementing stewardship practices and answering questions about them. It’s critically important to identify for community members where they can go if they have concerns about what might be happening about data. Yet many of the communities who participated in our discussions had not clearly identified one or more loci of accountability much less taken steps to make members of the public aware of these.

Second, assuring transparency. It’s really important for community members to be able to find out what’s happening with data. This is a critical way to avoid suspicion and shut down. But how to be effectively transparent, some ideas include use of websites, communicating with community leaders, using communications through channels through community organizations, but another possibility is of course the source of some of the data itself, the use of social media.

Finally, stewards need to pay attention to the lifecycle of data and this includes what you do with data when you’re done with it and it also includes following up when you transfer it. A standard method now used for data transfers is the data use agreement. This is the form of contract but it’s a very problematic enforcement method in this area because it involves just the two parties to the contract, contract damages don’t include punitive damages. The measures of damages, particularly if they are to third-parties, may be very difficult to figure out. And we know very little about what happens downstream with respect to data use agreement.

So these are just three of the areas that I think our toolkit tries to provide tools for communities that might be interesting for you to look at, but I think there’s a lot more to be done in order to ensure appropriate community trust when big data are used and I would highlight not only the very difficult questions associated with things like the efficacy of de-identification, but also just much simpler questions like who has responsibility, where do you go, how do you know and how do you follow-up? Thanks very much and I look forward to the discussion.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Great, thank you very much, Leslie, much appreciated. So now we’ll move into the question period. I don’t have any hands up yet at least I don’t think I do. So, I’ll go ahead and ask something. I’m going to ask a question specifically to Leslie here but Melissa if you have any thoughts on it I’d appreciate it.

So, I want to go to the data use agreement issue that you just raised and I don’t know if you’re familiar with some of the work that Bob Gellman has done on trying to make data use agreements more sort of legally enforceable but he raised it when he gave his presentation on Friday.

You know data use agreements look very appealing, I think, as one measure, not the measure, but a measure of accountability because you have the flexibility to sort of make them contextual it’s not one-size-fits-all, but as you brought up the issue of, you know, how do you enforce those especially if the party in the position of enforcing them is just not interested in pursuing enforcement, are they a tool that we just…are data use agreements just not a direction we should head in or are there ways to strengthen them, are they one part of a solution but not the whole part? What…

**Leslie P. Francis, JD, PhD – University of Utah School of Medicine – National Committee on Vital & Health Statistics**

My view is that they’re only one part.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Okay.

**Leslie P. Francis, JD, PhD – University of Utah School of Medicine – National Committee on Vital & Health Statistics**

And I guess a couple things just to point out about that. And I will say that I teach contracts in the law school so this is a little bit of an analysis coming from a contract’s law professor here. They are agreements between the initial older of the data and the party with whom the data are being shared. One of the beneficiaries of that agreement are the data subjects, but they’re not direct parties to agreement. So under contract law they’re what are called third-party beneficiaries.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Right.

**Leslie P. Francis, JD, PhD – University of Utah School of Medicine – National Committee on Vital & Health Statistics**

And in order for third-party bene’s to have rights to suit they are, you know, a complex set of contract law doctrines about whether the contract was intended to benefit them. So, in the area of health there have been third-party beneficiaries that have been able to bring suit when there have been contracts between employers and HMOs to provide healthcare to the employees. But I don’t know of any cases at all in which there has been any kind of effort on the part of a third-party beneficiary to enforce a data use agreement to bring suit on one for damages.

I also would note that it is the initial holder of the data has different interests in protection of what’s in the data use agreement then do the third-parties. So reputational interest, for example, might loom large for the initial holder of the data if their reputation as a trustworthy data collector turns out to get questioned by what happens downstream. So their interest in investigating what the downstream holders of the data are doing might be different…

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Right.

**Leslie P. Francis, JD, PhD – University of Utah School of Medicine – National Committee on Vital & Health Statistics**

From the interest of the third-party beneficiary. That’s just one problem. Another problem is that their damages for breach of contract might be very different and contract law does not allow anything like punitive damages which would be the kinds of damages used…well, a fine for example is an enforcement mechanism that could easily send a message to others.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Right.

**Leslie P. Francis, JD, PhD – University of Utah School of Medicine – National Committee on Vital & Health Statistics**

And I don’t see that happening with respect to what would be available in any kind of breach of contract litigation. So, those are just a few reasons.

Also I don’t think when their data transfers, from what I know, there’s a lot of follow-up, regular checking for example to make sure that data use agreements are being appropriately complied with. People just sort of figure they’ll sit back and if something bad happens then they might take action in the research context that would look like for example research misconduct. But, those are my thoughts and I would appreciate any feedback from the rest of the group.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

That’s helpful, Leslie, thank you very much. We have some other Workgroup members tee’d up for questions so I’m going to turn to the queue. Linda Kloss?

**Linda Kloss, RHIA, CAE, FAHIMA - President at Kloss Strategic Advisors, Ltd.**

Yes, thank you and thank you Leslie for summarizing this work. I think there are three points that this work kind of underscores. One is, you know, we started this realizing that community had a lot of different definitions. And I think that’s relevant to the work of our Workgroup here. It could be a community of interest or it could be a geographical community but we define that very broadly and really looked at the full range of sophistication, but what was common was that a lot of these uses really fell outside of HIPAA so I think in that regard it echoes a lot of the conversation over the last, you know, eight hours of very wonderful testimony and so therefore, went back to the fair information practices.

But I think it calls up I think perhaps some lessons that we’ll think about going forward. Should we be starting with big data and I’d like Melissa and Leslie’s…do we start with the notion of the data or do we start with who is using it, because I think that makes such a big difference.

And then can the fair information practices be framed as we’ve tried to set out to do with the community as a way of laying the groundwork and then addressing kind of the range of sophistication because we’ve heard a full range in this testimony and all of the technology and the shortage of resources to guide this.

So, I think community, fair information practices and really the range of sophistication and should we be thinking about framing this starting with the data or starting with the use cases?

**Leslie P. Francis, JD, PhD – University of Utah School of Medicine – National Committee on Vital & Health Statistics**

You know it’s hard, if I can just weigh in, I couldn’t agree with you more on everything you said. I mean, I think what you said is just dead on.

And I would also emphasize that not only is all of this outside of the realm of or much of it outside of the realm of HIPAA although there may be, if data from clinical records are used, there may be transfers of data that was originally HIPAA protected into spheres where it is outside of the realm of HIPAA either by patients themselves and to vehicles like personal health records or via transfers from the original covered entity.

I think HIPAA is not a good model to start with because it’s back in the old days where we are looking at either consent as Barocas and Nissenbaum outlined or de-identification as modes of protection and we just need to think differently.

So, you raise the question of should we be doing this by type of data or by data holder and one of the standard views that really goes against the grain of the way our whole privacy law has been structured in sectorial fashion is that wherever the data are they should have the same type of protections, because if you give health data to your physician and then you have it downloaded into some kind of public health repository, and you find out that it doesn’t have the same protections in the latter that it did in the former, that’s an immediate mechanism for the kind of concerning surprise that could lead people to start to question really important forms of data use.

So, I think we need to rethink all of this in terms of how do we try to provide, as much as we can, against the back drop of our crazy “privacy law” both federally and state. How do we try to build in some minimum consistent standard and FIPS are as good as any place to start. The list that Melissa gave which is largely drawn from FIPS is, you know, a great place to use as a starting place to start thinking about these kinds of issues.

**Melissa M. Goldstein, JD – Associate Professor Department of Health Policy – George Washington University**

This is Melissa. I agree completely with Leslie. And I would note that, you know, her work is a much more research oriented work than what we might see in the New York Times, right? But the New York Times has been great at reporting these incidents of big data analytics where, you know, people find out that they’ve been labeled as a diabetes concerned household or that now, you know, Target knows they are pregnant before their family knows that the women is pregnant, right, things like this.

And it’s really the element of surprise that how in the world did you get this information in the first place and why are you now allowed to use it in a way that you’re telling other people things about me? That’s really where people really feel the insult and the indignity and when it affects a group, however you define the group, whatever their commonalities are, it’s amplified.

I think that the FIPS are as good as place as any to start. I think that they’re sound and that they have, you know, held true over time and like I said, you know, they really overlap with that group of basic bioethics and public health principles.

I also, you know, back to Deven’s question about the data use agreements, I’d rather have data use agreements than not have data use agreements, but I think, you know, it’s one of the tool chests that we have to use.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Thank you, to both of you. David McCallie?

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Yeah, so now you have a question a from a non-lawyer and one that Taskforce will have heard me ask before and they’re probably tired of me asking it, but it seems like if we have accountability and can hold people to fair information use-based contract that’s one thing but what about the harms that occur when the data is exposed that are completely downstream from the data use agreements or contracts or fair information practices?

Do we need additional mechanisms to address the harms and the examples that we’ve called out in earlier parts of our discussion include ACA and pre-existing conditions not disallowing health insurance, redlining prohibitive, discrimination prohibitive and so forth. I just wonder if accountability for fair information practices addresses part of the problem but once the data is out the harm can still occur.

**Leslie P. Francis, JD, PhD – University of Utah School of Medicine – National Committee on Vital & Health Statistics**

You’re absolutely right that’s why I think it’s only part of the toolkit.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Can you see particular avenues where we should pursue the harm question in this big data era that are not well addressed by current laws?

**Leslie P. Francis, JD, PhD – University of Utah School of Medicine – National Committee on Vital & Health Statistics**

Well, one of the things the primary way that all of the use of data outside of the realm of HIPAA is addressed is under the Section 5 of the Federal Trade Commission Act. So unfair or deceptive trade practices so if you lie about what you’re doing with data or if you use data, and there are few cases that sort of look like this, if you use data in a way that creates an unacceptable risk that the consumer can’t protect about, can’t protect with respect to, so the failure to encrypt at machines where people’s credit cards get swiped, for example, but that might count as under FTC as an unfair trade practice.

But there have been various proposals about whether expansion of the FTC, whether the development of a whole new data regime for big data privacy. There are a variety of ways to go on that. And I guess a fundamental question is whether you want to try to start with what we’ve currently got because you don’t think you’re going to be able to get statutory change or whether you want to go along the lines with some of the kinds of efforts to introduce some more overarching privacy regime into American law.

**Melissa M. Goldstein, JD – Associate Professor Department of Health Policy – George Washington University**

I would note that we have been able as a society with greater or lesser success been able to identify things that we don’t want used against people, right?

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Right.

**Melissa M. Goldstein, JD – Associate Professor Department of Health Policy – George Washington University**

So we do have the disallowance of pre-existing conditions in the ACA, no matter what you think of the ACA, that did pass with it right? And GINA does prohibit discrimination in employment and insurance for genetic information but it only applies to certain insurers, it doesn’t apply to long-term insurance, home healthcare that sort of thing.

So we haven’t been perfect but we have been able to make decisions about things that we don’t want people to use data for with gaps, with a whole lot of gaps, but we have made it there in the past.

**Leslie P. Francis, JD, PhD – University of Utah School of Medicine – National Committee on Vital & Health Statistics**

That’s right. GINA is really interesting example because it prohibits both getting the information and of course a lot of employment discrimination law works by prohibiting employers from making discriminatory use of the information.

And the unfortunate problem about relying on after-the-fact challenges to denials or what might happen if an employee who turns out to be expensive on a health plan starts getting poorer performance evaluations, but the damage can happen before anybody knows about it.

And any kind of use of employment discrimination law is unfortunately you’ve got to suffer the discrimination, recognize that you’ve suffered it and then turn around as the individual who suffered it and bring the litigation.

So it is much better, I think, to start with some minimal upfront standards then to start about you just can’t either get or use certain kinds of information or if you do you have to use it subject to certain kinds of protections whether those might be even just simple kinds of protections like transparency so that people know what might be out there with respect to data uses. That’s a much better way to go, I think, then relying on individuals after-the-fact to identify harms and then take action based on them.

**Melissa M. Goldstein, JD – Associate Professor Department of Health Policy – George Washington University**

One of the…

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

So, if I…

**Melissa M. Goldstein, JD – Associate Professor Department of Health Policy – George Washington University**

I’m sorry, go ahead.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Well, I was just going to say…so I want to turn that back around to your example of Target and identification of the pregnancy without any…before anybody else knew about it, where in that process did somebody violate FIPS? I mean, what’s wrong with what happened there? How would what you propose address that if it would at all?

I mean, it was certainly a surprise to the consumer but that’s standard marketing strategies to use the data to figure out what you might buy that would certainly have been in their disclosure had there been such a disclosure. How would it be harmful?

**Leslie P. Francis, JD, PhD – University of Utah School of Medicine – National Committee on Vital & Health Statistics**

Melissa, that was your example, do you want to start with that?

**Melissa M. Goldstein, JD – Associate Professor Department of Health Policy – George Washington University**

Well, I think the first problem is that there was no disclosure, right? So, people would have no idea what they’re getting themselves into and, you know, I was shopping over Black Friday and forgot to turn on my private browsing and then the purse that I was shopping for showed up for the next week on every website I went to somehow, right, that’s my…I view that as my own fault because I know these tricks, right, but the disclosures for the first part perhaps the use limitations really, use of the data. So, first disclosing what you’re going…what the purpose of the collection is and then later on actually using the data for what you say you collected it for those sorts of areas.

What I was going to say a moment ago was I mentioned in my brief testimony that the article that Frank Pasqaule and I wrote suggested potentially requiring changing the ways that data collectors maintain their databases and what we’re talking about then very briefly and not much detail in the article, which I’ll submit the Workgroup to look at, is the idea of the metadata tagging within the databases so that information in the health sphere that is health related can be tagged as such and basically never be used for things such as employment if employers are trying to get information from the data brokers, that sort of way. So, maybe we could use metadata tagging in ways that we haven’t thought of it and actual data collectors have to use it things like that.

**Leslie P. Francis, JD, PhD – University of Utah School of Medicine – National Committee on Vital & Health Statistics**

You know just to add onto that another way to use metadata is to identify…to provide a downstream way of identifying who’s accessed and used it. You can keep…with metadata you can keep an ongoing way of providing an accounting for disclosures.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

We had…this is David again, we…in our session last week somebody made the statement that essentially all data is health data in some circumstance so I wonder if there are limits to how useful the tagging would be.

I mean, everything you do, how far you walk, where you go, what you eat, what you buy all of that has health consequences and obviously the population health management companies are trying to take advantage of that to minimize the risk in population that they are accountable for.

**Melissa M. Goldstein, JD – Associate Professor Department of Health Policy – George Washington University**

I would agree and, you know, back to the Target example, I think the term that we use standard marketing procedures, right, I think in a way that’s a value judgment. We’re saying that what they do now is the same as what they’ve always done and they’re trying to figure out what to sell to us and, you know, it could be a purchase of a large bag, a light blue rug and zinc supplements and therefore they decide that I’m pregnant, right? And this is the way that marketing works.

Well it’s a little different now with big data analytics. So, do we believe that standard marketing procedures are…is that a value judgment that we’re making that that’s untouchable or does that have some element that we can affect as well especially if people are deriving a health status from the information.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

I’ll let somebody else jump in, this is a fun conversation but I don’t want to monopolize it.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Okay, thank you, thanks David I was just looking with my eye on the time and we do have a couple more folks with hands up. Gil?

**Gilad J. Kuperman, MD, PhD, FACMI – Director Interoperability Informatics – New York Presbyterian Hospital**

Hi, this is a great discussion about a very difficult topic. I was going to invoke the New York Times but Melissa beat me to it. There was, you know, an op-ed today about Uber’s database and, you know, what happens if Uber knows that you’re going to a cancer center, you know, what are the ramifications of that and what can they do with that data and things like that, you know, among other data in their database so, you know, it’s the same kind of things that we’ve been talking about here and how does that get controlled in some way and I think we’ve kicked around a lot of options.

But one question I have for the panelists is what is…what do you think is the sense of urgency societally around the need for change here and, you know, we’ve talked about, you know, whether it’s FTC or FIPS, or other approaches, do you think there’s an appetite for change or do things need to get worse before, you know, there will be some societal appetite? Where do you think we are in that spectrum?

**Leslie P. Francis, JD, PhD – University of Utah School of Medicine – National Committee on Vital & Health Statistics**

So, one, you know, one question is how much of an individual appetite is there and, you know, I think that varies. There is some data, Hoofnagle’s data, to the effect that people think they have more in the way protection than they actually do, particularly younger people who are frequently cited as not caring about privacy.

I don’t actually think the individual appetite is the only way to grab…to come at the question of whether we need to be thinking about adequate protections and that’s because it only takes one really bad event to get a shut down on what might be extremely important constructive uses of data.

And, you know, my…the two examples where that actually happened was Texas’s destruction of millions of newborn screening blood spots and of the extraordinarily valuable public health information that they contained. And then Minnesota is now destroying I think it’s…the figures I just saw where 200 a day so it’s…what you don’t want is to just leave the area unexamined and then turn out to have a crisis.

**Gilad J. Kuperman, MD, PhD, FACMI – Director Interoperability Informatics – New York Presbyterian Hospital**

Thank you.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Hey, Deven, this is Lucia, can I ask one last question before we go to the public session?

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

Deven, you might be on mute.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

In fact I was, sorry about that, go ahead, Lucia.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Just a really quick question I think it’s for Leslie. Leslie, can you just really briefly tell us whether…give us examples why the communities that have adopted all or part of your toolkit or are considering it and I sort of say that in the context of thinking about the National Committee for Vital and Health Statistics I know they’ve very interested in this as well and there was some great testimony on Friday about communities wanting to better use data to address their needs. So, I’m really interested in whether that toolkit is kind of in implementation anywhere?

**Leslie P. Francis, JD, PhD – University of Utah School of Medicine – National Committee on Vital & Health Statistics**

Well, the toolkit is just in draft form so it’s…

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Okay.

**Leslie P. Francis, JD, PhD – University of Utah School of Medicine – National Committee on Vital & Health Statistics**

We’re having the big launch probably in January.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Okay, good luck with that.

**Leslie P. Francis, JD, PhD – University of Utah School of Medicine – National Committee on Vital & Health Statistics**

What I can say…

**W**

But it was developed with a lot of input from communities across the country.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

No, no I got that I just wondered if it had like gone in, gone to market as it were where people were actually using that in and there was, you know, a data omnibus person or whatever?

**W**

No.

**Leslie P. Francis, JD, PhD – University of Utah School of Medicine – National Committee on Vital & Health Statistics**

No, some of what we actually have in it are examples that are drawn from communities who have been implementing some of these techniques successfully.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

So, on that note, Leslie, you’re getting it ready for public release, you know, we certainly would love to see it when you’re ready to share it. You know we have our hearings…we had one last Friday as you know, the one today, we’re not likely to really dig in and start discussing this in earnest…I mean, we’ll begin some discussions next week but we’ll really start digging in in January. So, I think from a timing perspective it may work out just right.

**Leslie P. Francis, JD, PhD – University of Utah School of Medicine – National Committee on Vital & Health Statistics**

Well, I sent you, as part of the background materials for this hearing the draft which the only real changes in it will be making sure that we go through it one last time for typos and there are some formatting things. But you’ve got all the content.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Oh, great, terrific and Melissa we also are eager to get the two articles that you mentioned.

I’m going to actually take…there’s like a minute…well there is a minute that I had left I just ate up with my little introduction to my question, but I’m going to go ahead quickly ask it anyway before we move into public comment and that is, you know, you talked about the sort of data protection laws so that we don’t have the sort of sector specific laws that, you know, have data protected when it’s in some entities hands and not protected when it’s in others and that seems kind of crazy when, you know, the data are sort of moving out in various venues at a rapid rate.

But one thing that has always puzzled me with sector, sectoral laws is how do you make them contextual? I mean, if you think about HIPAA being very specific about healthcare operations and the types of uses that are customary for providers and plans, you know, that’s not going to fit for Google and Microsoft, and Facebook, and others.

How is there a law that actually works that is a data protection law but doesn’t respond to the different needs of the different context?

**Leslie P. Francis, JD, PhD – University of Utah School of Medicine – National Committee on Vital & Health Statistics**

So, you can have a very basic framework.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Okay.

**Leslie P. Francis, JD, PhD – University of Utah School of Medicine – National Committee on Vital & Health Statistics**

For example, that includes accountability, that includes some level of transparency, that includes at least a requirement that you need to think through what you’re doing with the data across a lifecycle.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Right.

**Leslie P. Francis, JD, PhD – University of Utah School of Medicine – National Committee on Vital & Health Statistics**

And then have more extensive or at least non-conflicting standards for particular realms of data.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Got it. Okay, appreciate that. All right, now we really are a bit past our time. I want to thank both of you very much for both your testimony today and also what you have shared with us in the past and what you’re going to share with us we very much appreciate it enormously helpful.

And with that I think we have some time on the agenda for both public comment and a wrap up. What tends to happens once we move into public comment is then we start losing folks so I’m going to go ahead and say we have had a wonderful two days of listening sessions.

We are still trying to get some folks to address us during our next Privacy and Security Working Group public call which is next Monday, a handful of folks who are unable to join us for either of these two listening sessions days that we are hoping that we might be able to grab for our regularly scheduled call on the 15th but otherwise we’ll use that time to start sharing our impressions of the hearing, going over some at least at a high-level some of the common themes that emerged and just really begin our discussion of this issue before we close out the year and pick it back up in the new year.

So, just wanted to let you all know about what our plans are going forward. Stan, do you have anything to add before we move into public comment?

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP**

No, just thank you to all the participants and the panelists, it was really extremely well done and we’re looking looking forward to diving in deeper now.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Okay, great. Thank you. And with that, Michelle, I think we’re ready to open to public comment.

**Public Comment**

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Operator, can you please open the lines?

**Caitlin Chastain – Junior Project Manager – Altarum Institute**

If you are listening via your computer speakers you may dial 1-877-705-6006 and press \*1 to be placed in the comment queue. If you are on the phone and would like to make a public comment please press \*1 at this time.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

We have no public comment. I just want to echo Deven’s thanks to everyone, thank you to Deven to you and Stan for helping to orchestrate everything and to the MITRE Team for pulling everything together. So thank you all we greatly appreciate all of your testimony.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Thank you, Michelle, everyone have a good rest of your day whatever’s left of it and a good week.

Public Comment Received During the Meeting

1. What's the impact of accelerating clinical pathways? I'm not sure how this works.

2. Not sure if this question has been asked, but have there been any consumer complaints or concerns that the panelists have faced in response to their nuanced uses of the data?

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Meeting Attendance | | | | |
| Name | **12/08/14** | **12/05/14** | **11/24/14** | **11/10/14** |
| Adrienne Ficchi |  |  |  |  |
| Bakul Patel |  |  |  |  |
| Cora Tung Han | X | X |  |  |
| David Kotz |  |  | X | X |
| David McCallie, Jr. | X | X | X | X |
| Deb Bass | X |  |  |  |
| Deven McGraw | X | X | X | X |
| Donna Cryer | X | X | X | X |
| Gayle B. Harrell |  | X | X | X |
| Gilad Kuperman | X |  |  | X |
| Gwynne L. Jenkins |  |  |  |  |
| Helen Caton-Peters | X | X |  | X |
| John Wilbanks |  |  |  |  |
| Kathryn Marchesini | X | X | X | X |
| Kitt Winter | X | X | X | X |
| Kristen Anderson | X | X | X | X |
| Linda Kloss | X | X | X | X |
| Linda Sanches | X | X | X | X |
| Manuj Lal |  |  |  |  |
| Mark Sugrue |  |  |  | X |
| Micky Tripathi |  | X | X |  |
| Stanley Crosley | X | X | X | X |
| Stephania Griffin |  | X |  |  |
| Taha A. Kass-Hout |  | X | X |  |
| Total Attendees | **13** | **15** | **13** | **14** |