



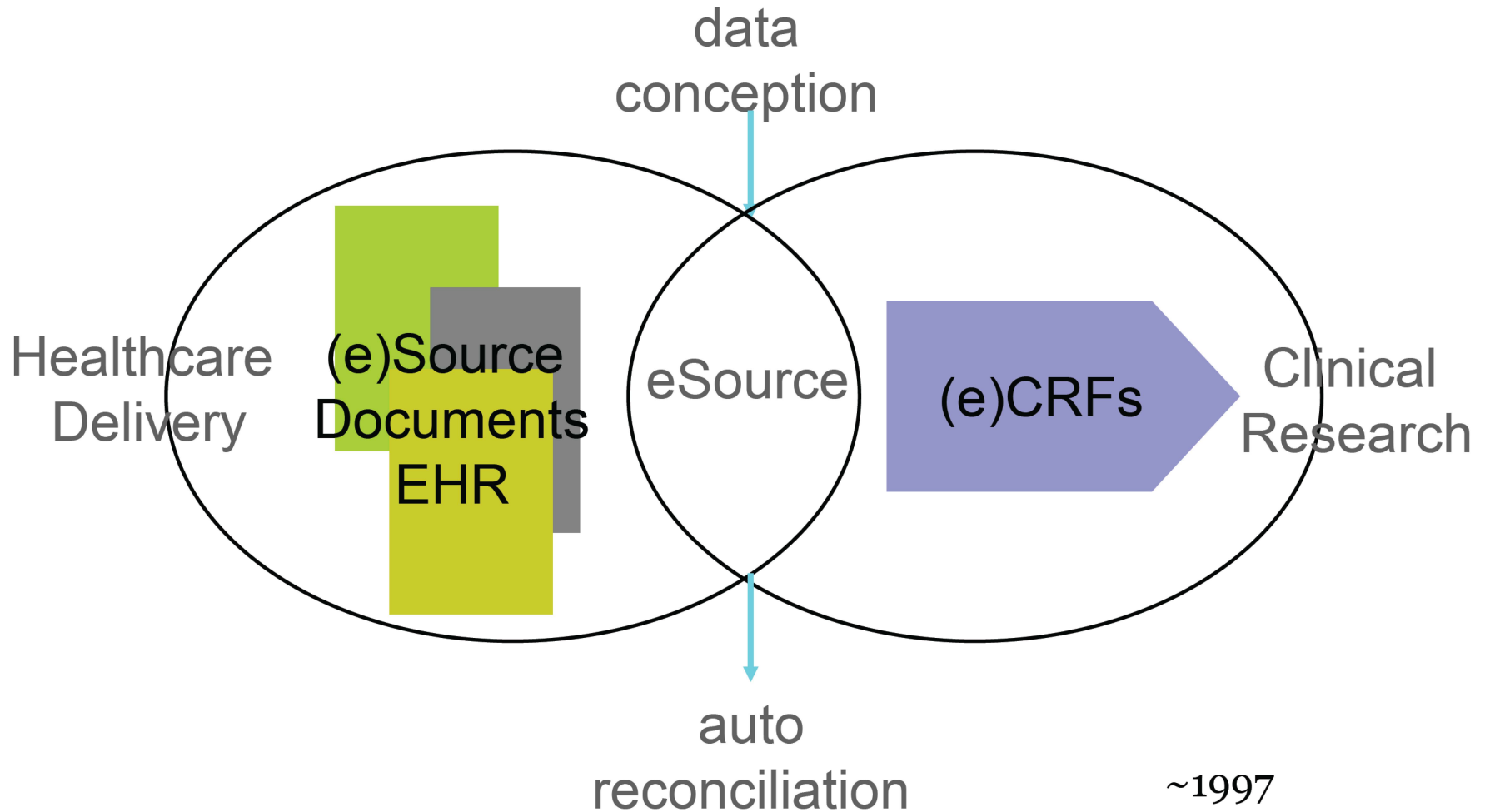
CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

Setting the Global Standard for Medical Research

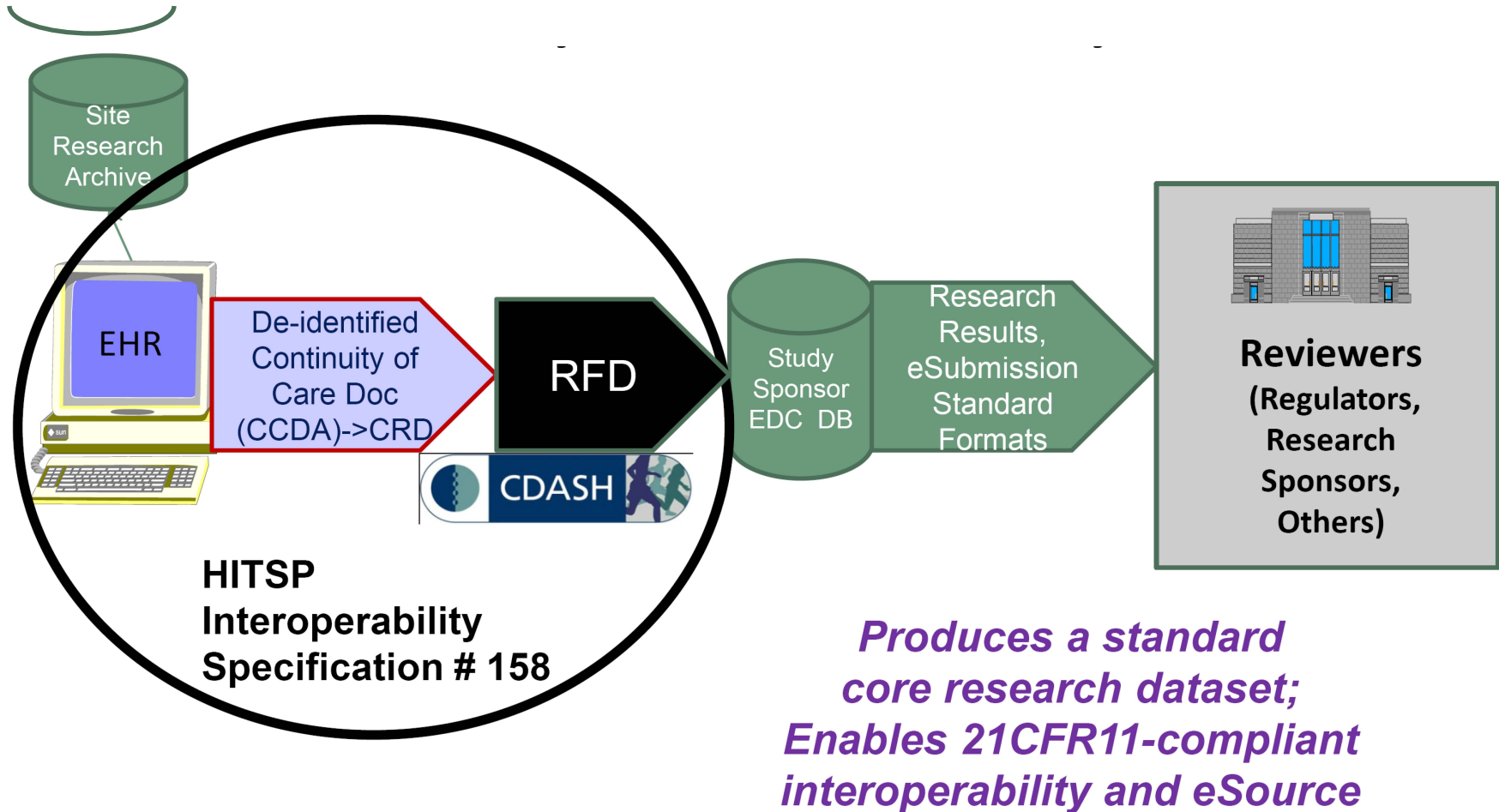


Strength through Collaboration

Healthcare Link Goal: Optimize the Research Process



Patient Value: Quality of Healthcare, Safety



**HITSP
Interoperability
Specification # 158**

*Produces a standard
core research dataset;
Enables 21CFR11-compliant
interoperability and eSource*

ASTER (AE Reporting from EHRs)

30 Ambulatory care physicians at Harvard
and Brigham and Women's

with Pfizer, CDISC, CRIX

Nov 08 – Jun 09, > 200 Reports Sent to FDA

Physician Reporting:

*91% of participating physicians had
submitted no ADE reports in the prior year

**During the study, participants reported an
average of approximately 5 reports in a 3
month time period*

*All participants reported at least 1 AD

** Process: Time to report decreased from
~35 min to < 1 min*



Capabilities with Available (Core) Data Standards and Integration Profiles/Interoperability Specifications (Standards-inspired Innovation)

- Dramatic reduction in time and effort to report core data for safety, research, public health
- Can accommodate eDiaries, patient-entered data
- Improved data quality
- Data can be more readily aggregated and analyzed or queried
- Extensible; paves the way for more complex research and clinical genomics for personalized healthcare
- Easily implemented by vendors; endorsed by EHRA

Healthcare

- Quality healthcare
- Informed decisions
- Personalized medicine
- Patient safety and privacy
- Public health
- Improved therapies
- Efficiencies/reduced costs

*Information from healthcare
(private, aggregated)
to enable research*



Research

- Discovery of new therapies
- Understanding diseases
- Testing/comparing therapies (CER)
- Assessing efficacy
- Monitoring safety
- Understanding responses (genomics, biomarkers)
- Public health/quality evaluations
- Post-marketing surveillance

*Research findings
to inform
healthcare
decisions*

Thank you!

