



CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

*The CDISC vision is to inform patient care & safety
through higher quality medical research.*

A decorative graphic consisting of several overlapping, wavy lines in shades of blue and green that transition into a horizontal bar with a diagonal hatched pattern.

Strength *through Collaboration*

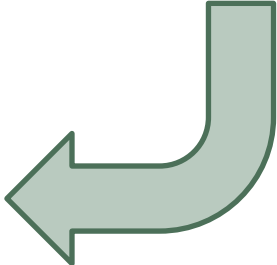
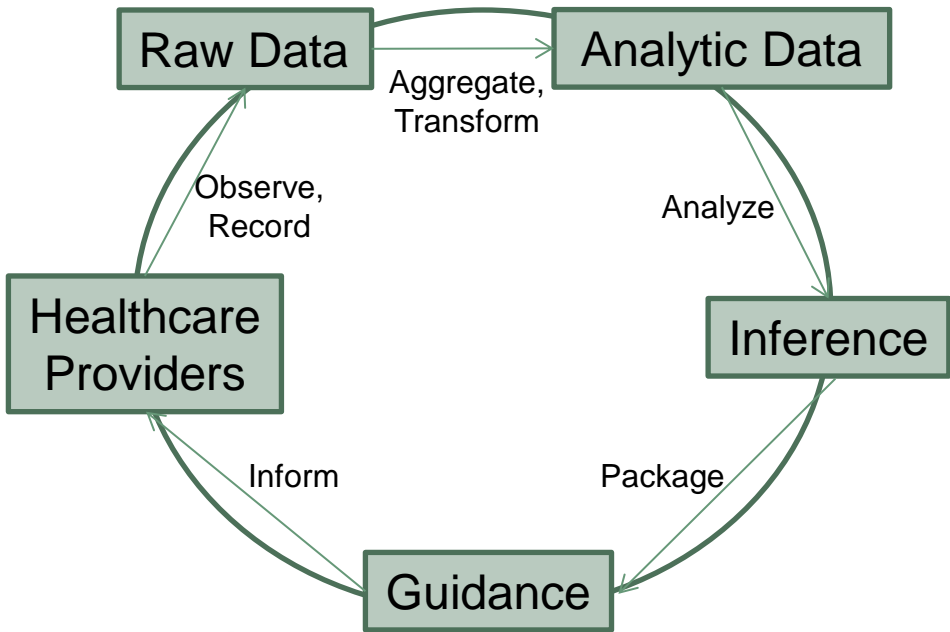
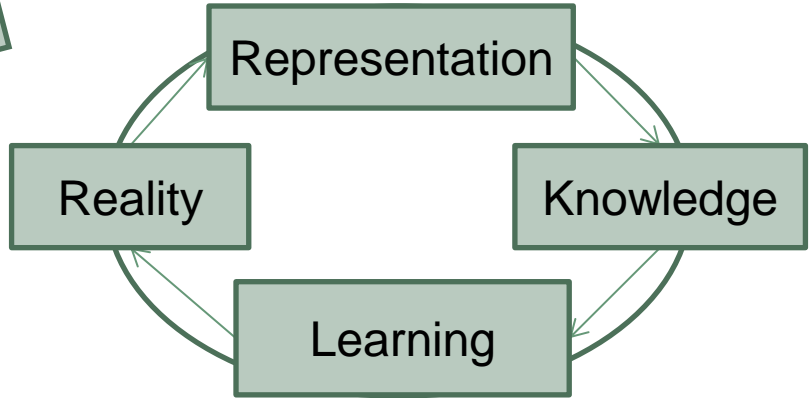
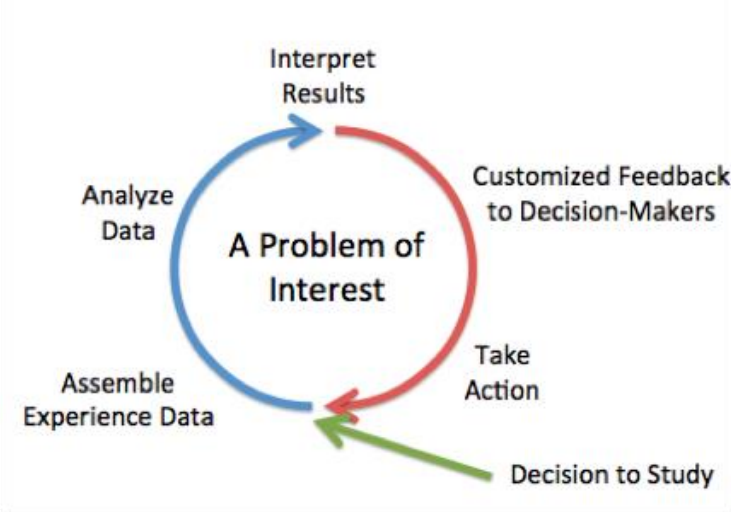
Essential Standards (and Structures) to Enable Learning

Landen Bain
CDISC

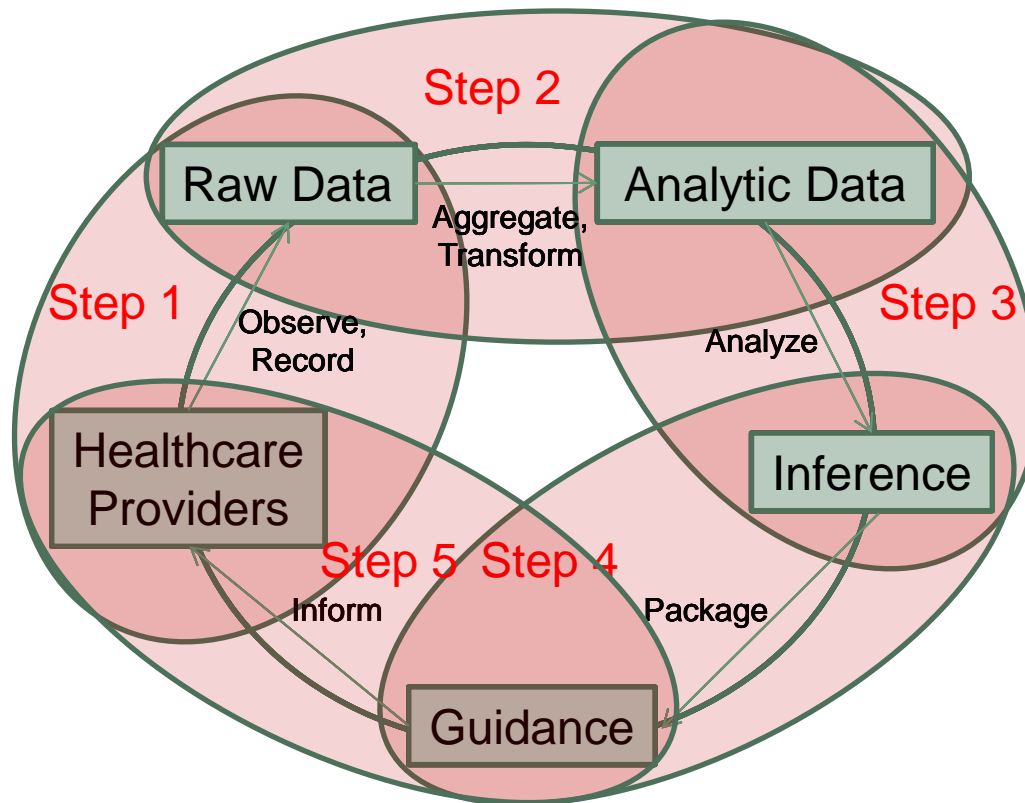


Strength through Collaboration

**Learning Cycle –
From Concept to Framework to
Entities and Activities**

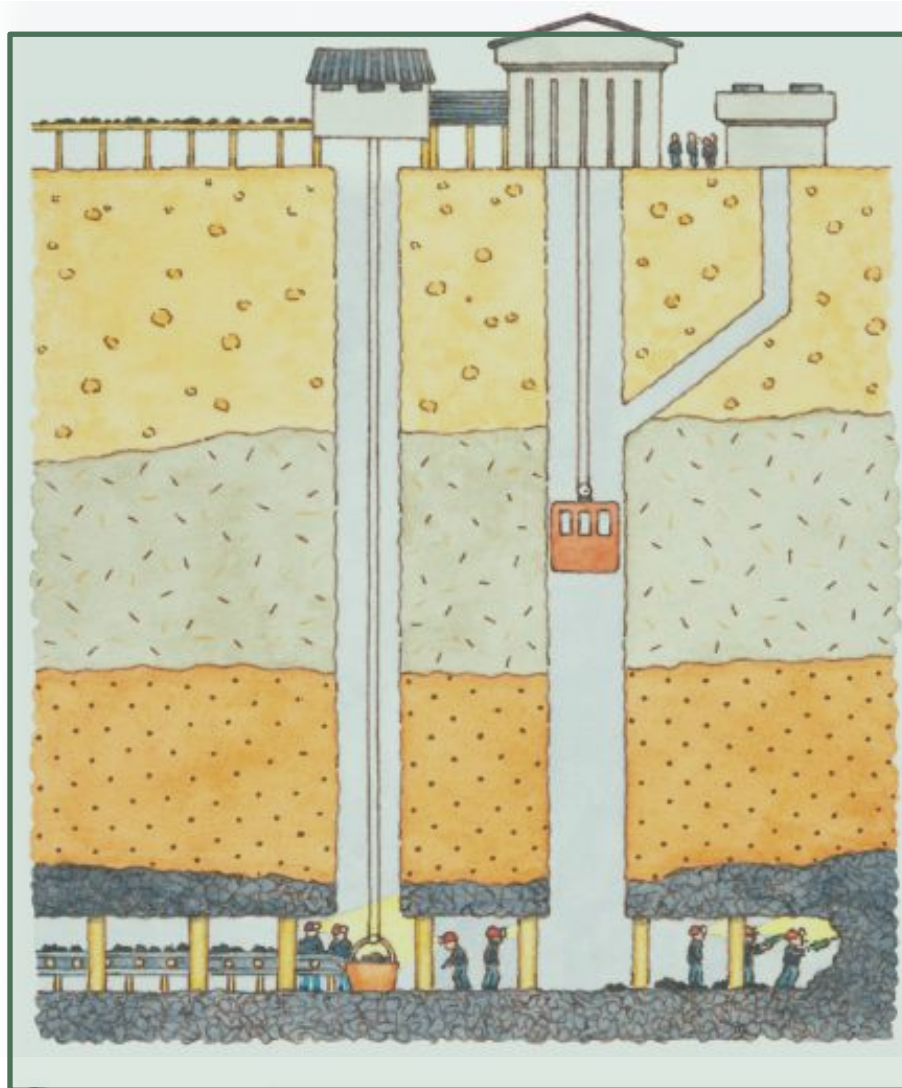


Five Steps of the Learning Loop Framework



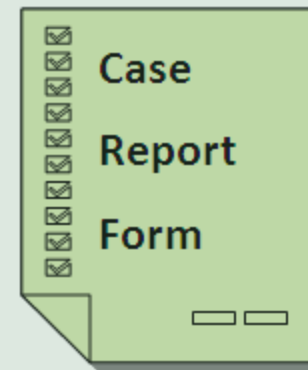
BIG DATA

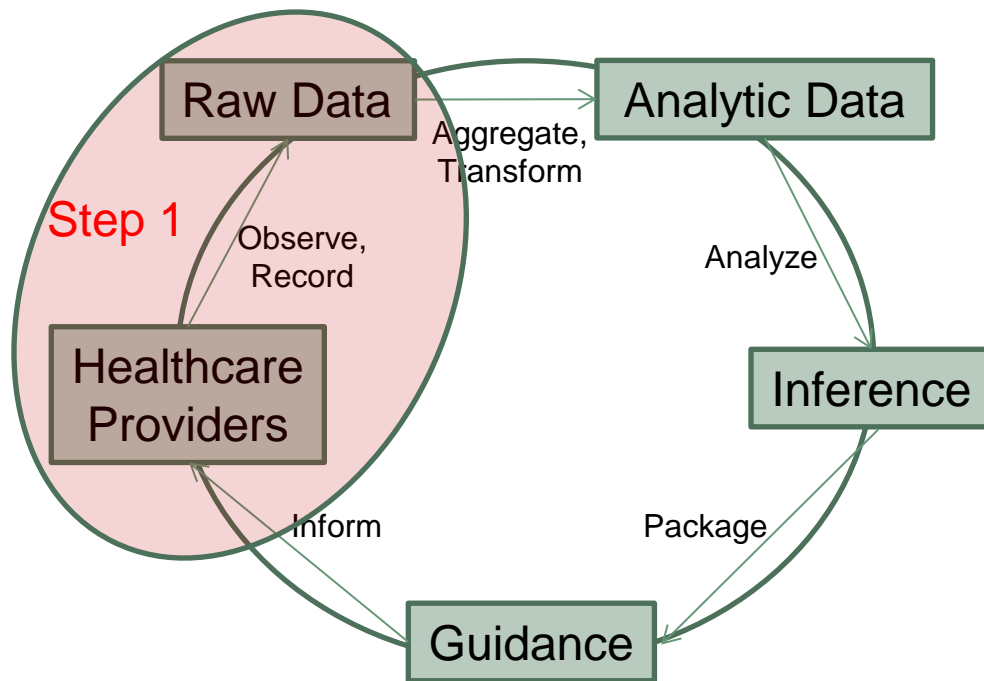
Data Mining



small data

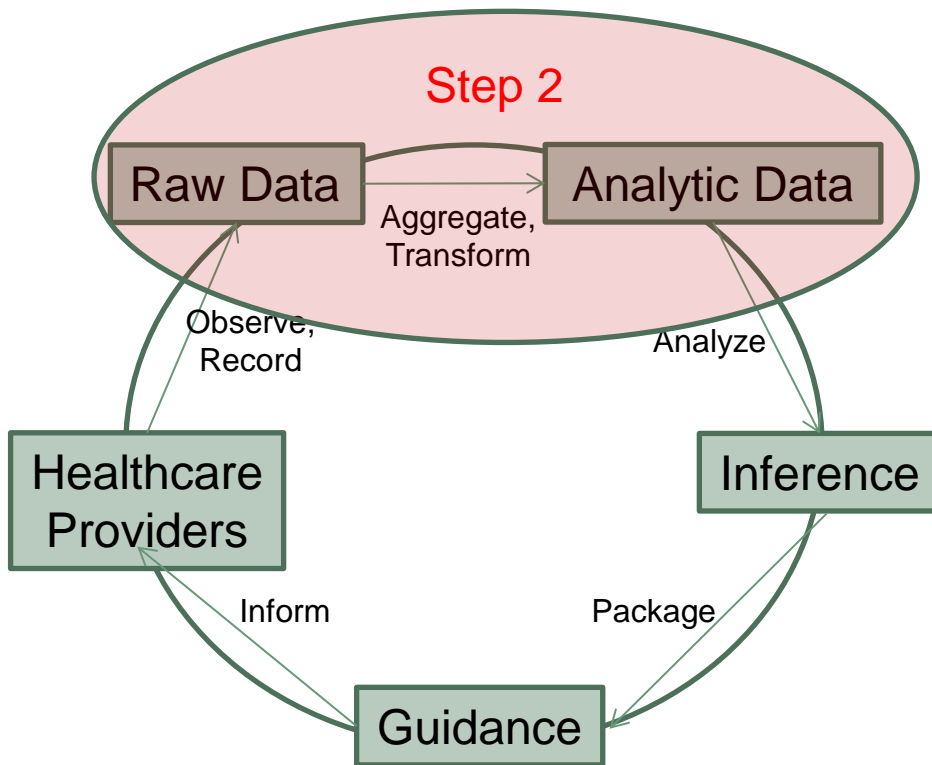
Structured Data Capture via Forms





Healthcare Providers observe and record events, thereby creating first order data

- This step is the foundation of all subsequent activities.
- Typically, this step occurs within the electronic health record or some other first order data capture system
- This step is mostly non-standard proprietary automation



Raw data get aggregated and transformed into an analyzable dataset

- This step often involves the export and re-use of EHR data
- CDISC Healthcare Link addresses this step: IHE's RFD, et al.
- HL7's CCD is the breakthrough standard

RFD Retrieve Form

I've got Mrs. Jones here for her catheterization and I need to **retrieve** her **form** so that I can do the **data capture**. And here's some data on her to start off.



Electronic Health Record



Registry System

Sure, here's the form we need for Mrs. Jones. I've inserted the data you sent me, and you do the rest.

RFD Submit Form

OK, here's the completed form. Thanks for inserting the data I sent you. I've completed the rest and filed a copy.



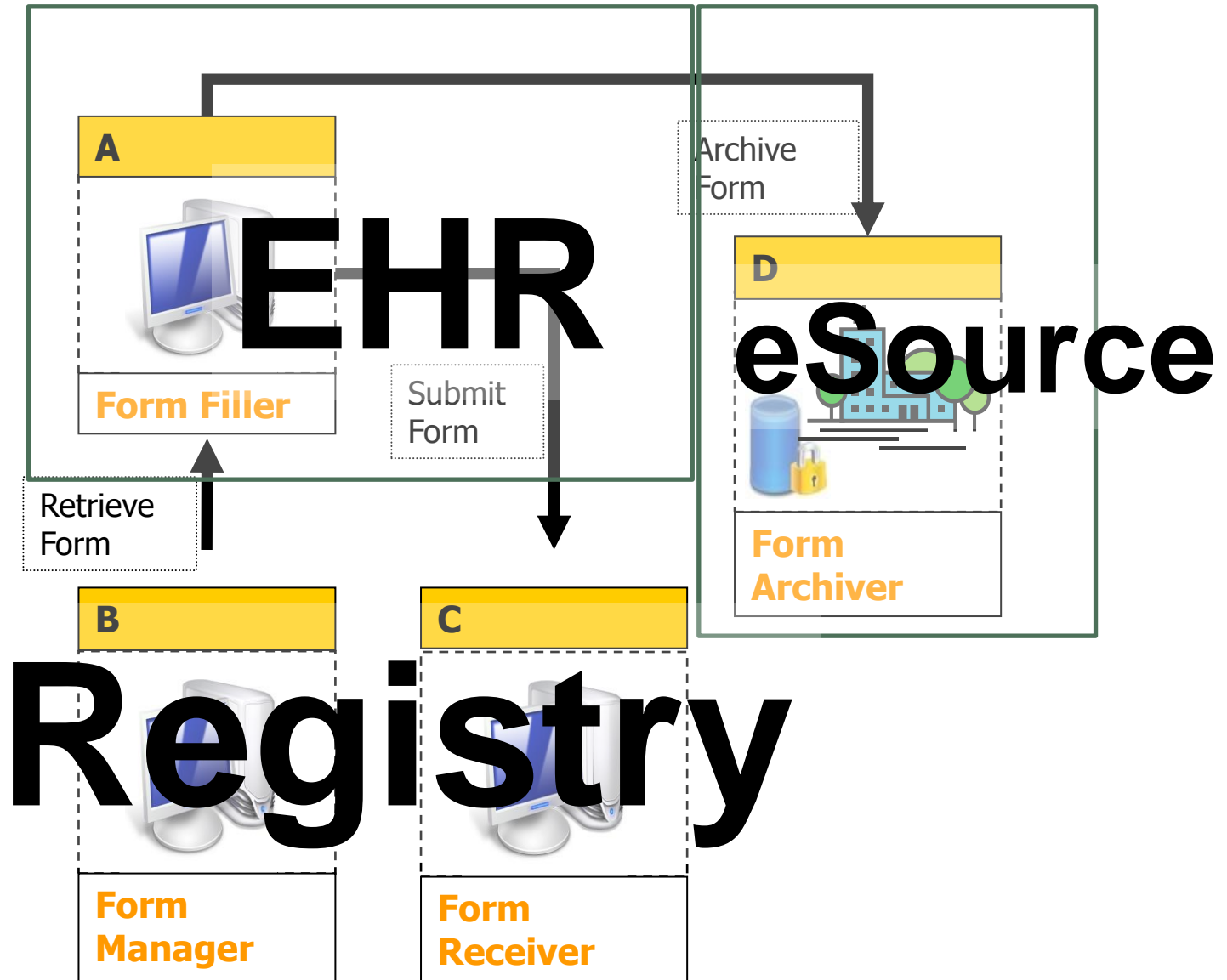
Electronic Health Record

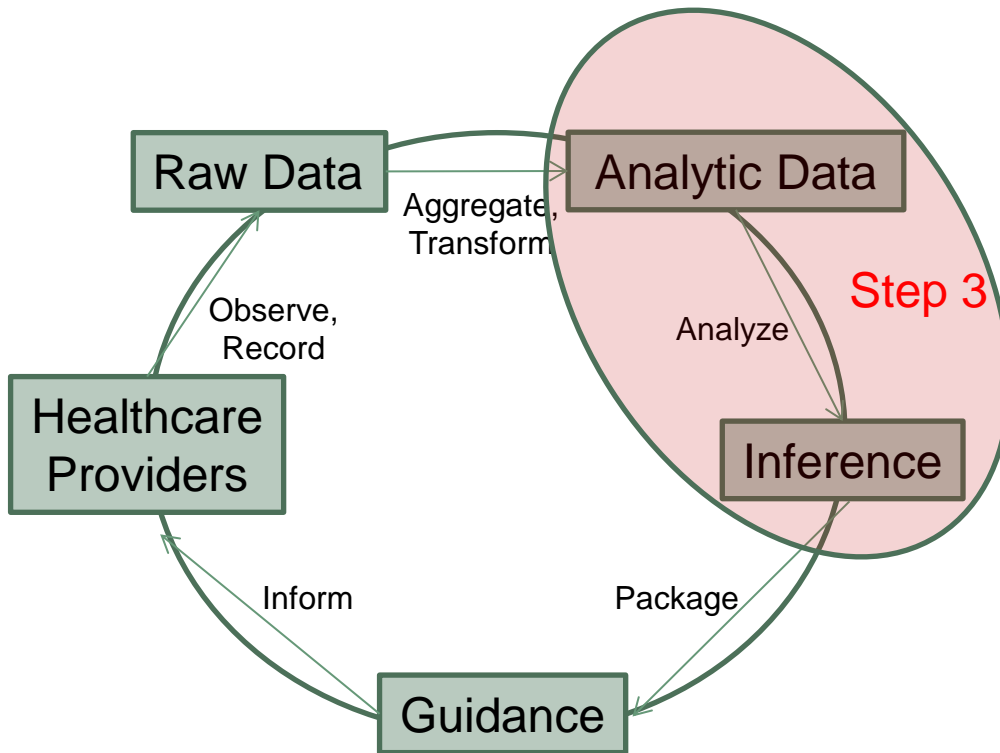


Registry System

OK, got it.

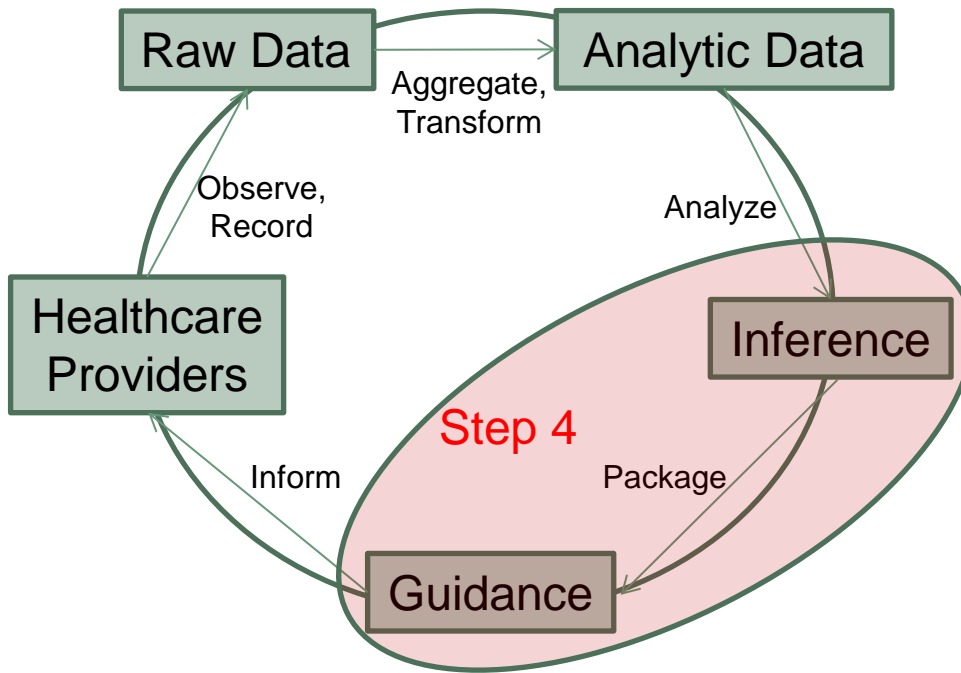
Retrieve Form for Data-capture (RFD)





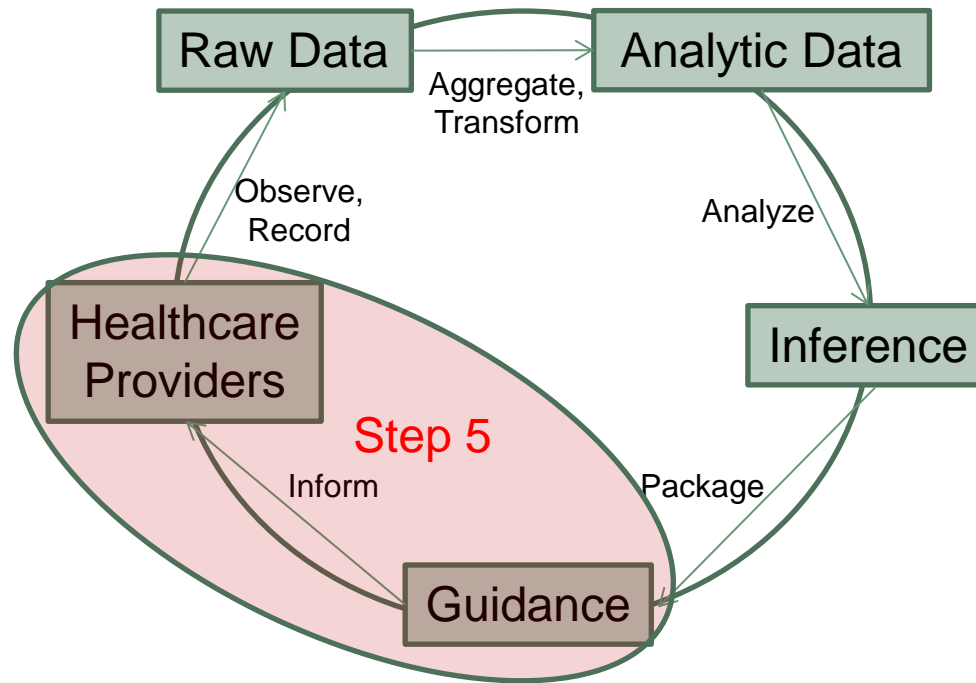
The analysis of the dataset produces inferences

- This step is the purview of biostatisticians in research, public health, and quality reporting.
- Often data must be reinterpreted
- CDISC's ADAM standards apply



Inferences get packaged as Guidances

- This step is often performed by professional associations
- Standards wasteland



Guidances Inform Healthcare Practice

- Access to guidances can occur within the EHR
- Access to guidance need to be triggered to the correct place in a practitioner's workflow
- To be effective, the guidance must be presented unobtrusively and concisely
- This is the weak link in the current learning loop automation
- GELLO ?