Considerations in the Development of Biorepository

Chirag R. Parikh, MD, PhD
Director, Division of Nephrology
Director, Precision Medicine Center of Excellence
Ronald Peterson Professor of Medicine
Johns Hopkins School of Medicine

AKI NOW

ASN
American Society of Nephrology

Components of Biorepository

- Informatics
  - Barcoding, GPS and location of aliquots and boxes
  - Patient consent, Reports (Real time inventory)
- Physical Component
  - Freezers, Alarms, Boxes, Aliquots
- Quality Assurance
  - Operating procedures, FDA guidelines,
  - Standardization
  - Audit Trail

Key Question

Leveraging a clinical research information system to assist biospecimen data and workflow management: a hybrid approach

Prakash M Nadkarni[1*], Rowena Kemp[1] and Chirag R Parikh[1,2]

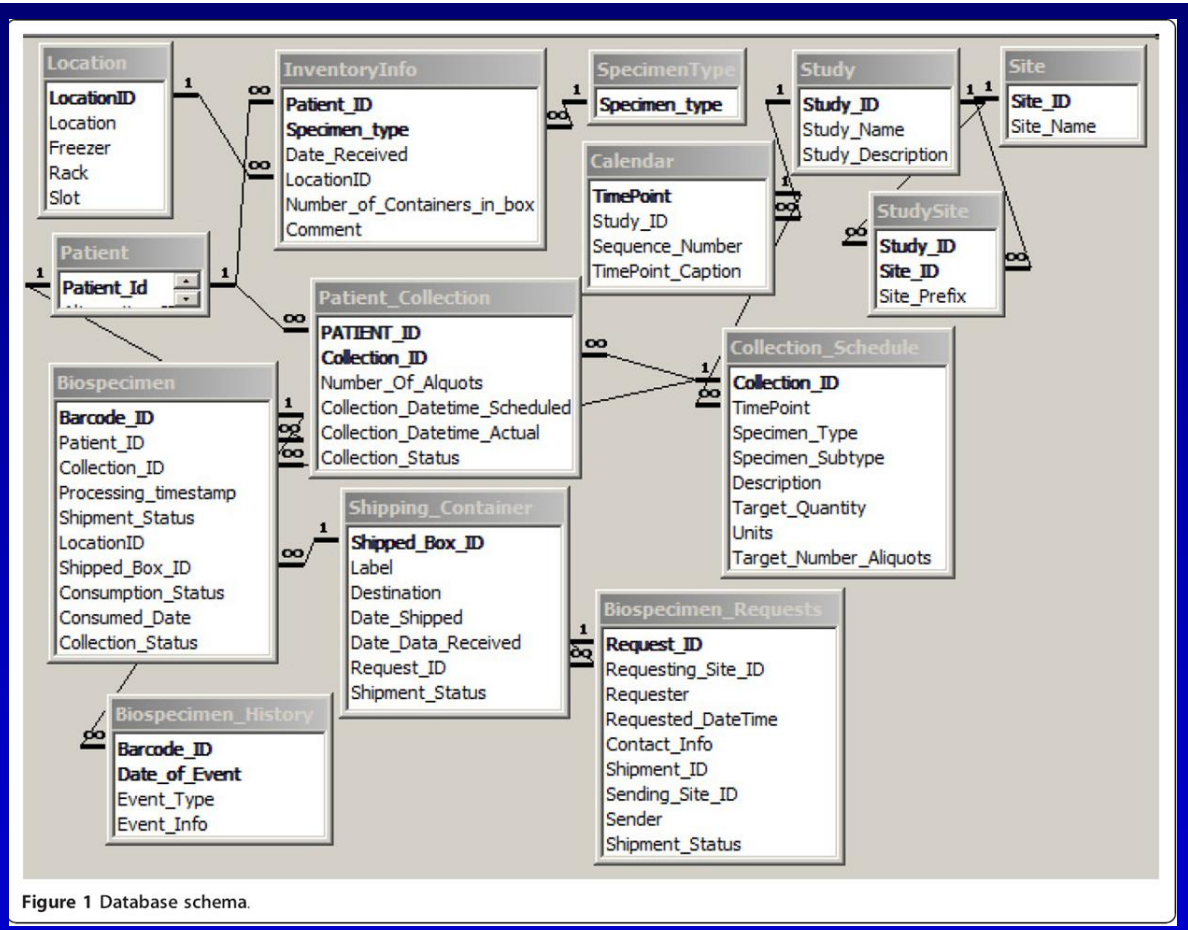


Figure 1 Database schema.

https://pubmed.ncbi.nlm.nih.gov/21884570/

JCBi JOURNAL OF CLINICAL BIOINFORMATICS

Detailed Information Captured

- Study Protocol Definition
- Specimen Characteristics
- Inventory Information

Specimen Characteristics

- *Sample Identification*
  - Barcode, Surrogate Patient ID, Protocol #, Site (for Multi-site studies), Specimen Collection Time (with respect to Protocol), Aliquot #
- *Biological Tissue used*
  - (e.g., Blood, Urine, DNA)
- *Status*
  - Not received, processed and stored, consumed
- *Timestamps*
  - Collection date, Processing Date, Consumption/Shipping Date

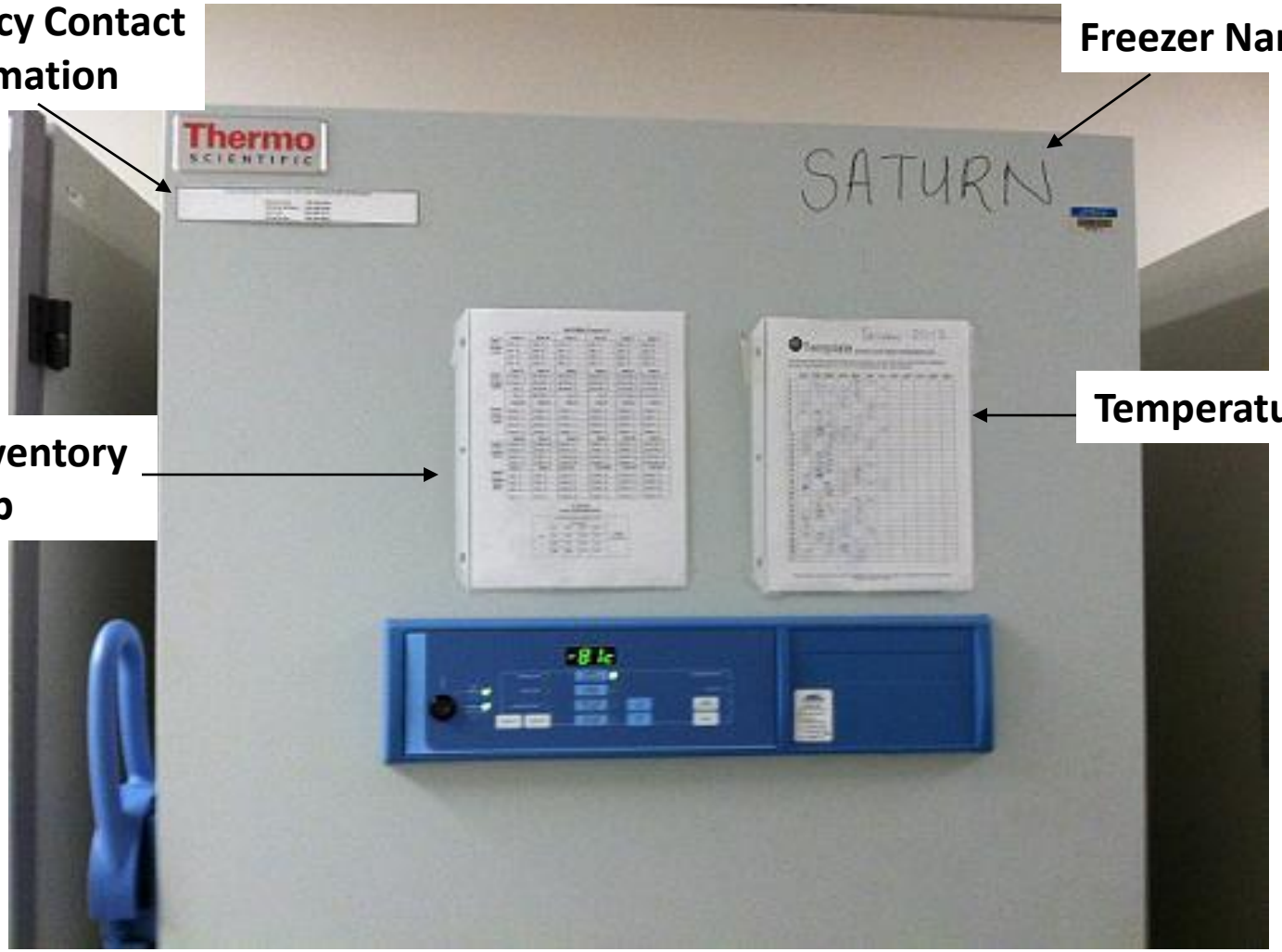
Inventory

- Master List of Locations
  - Freezers with Rack and Slot/Box Locations
- Location of individual Aliquots
  - Freezer, Rack, Slot/Box, Row, Column level
- Tracking history of location changes
- Aliquot Consumption
- Aliquot Trans-shipment

Feature Set

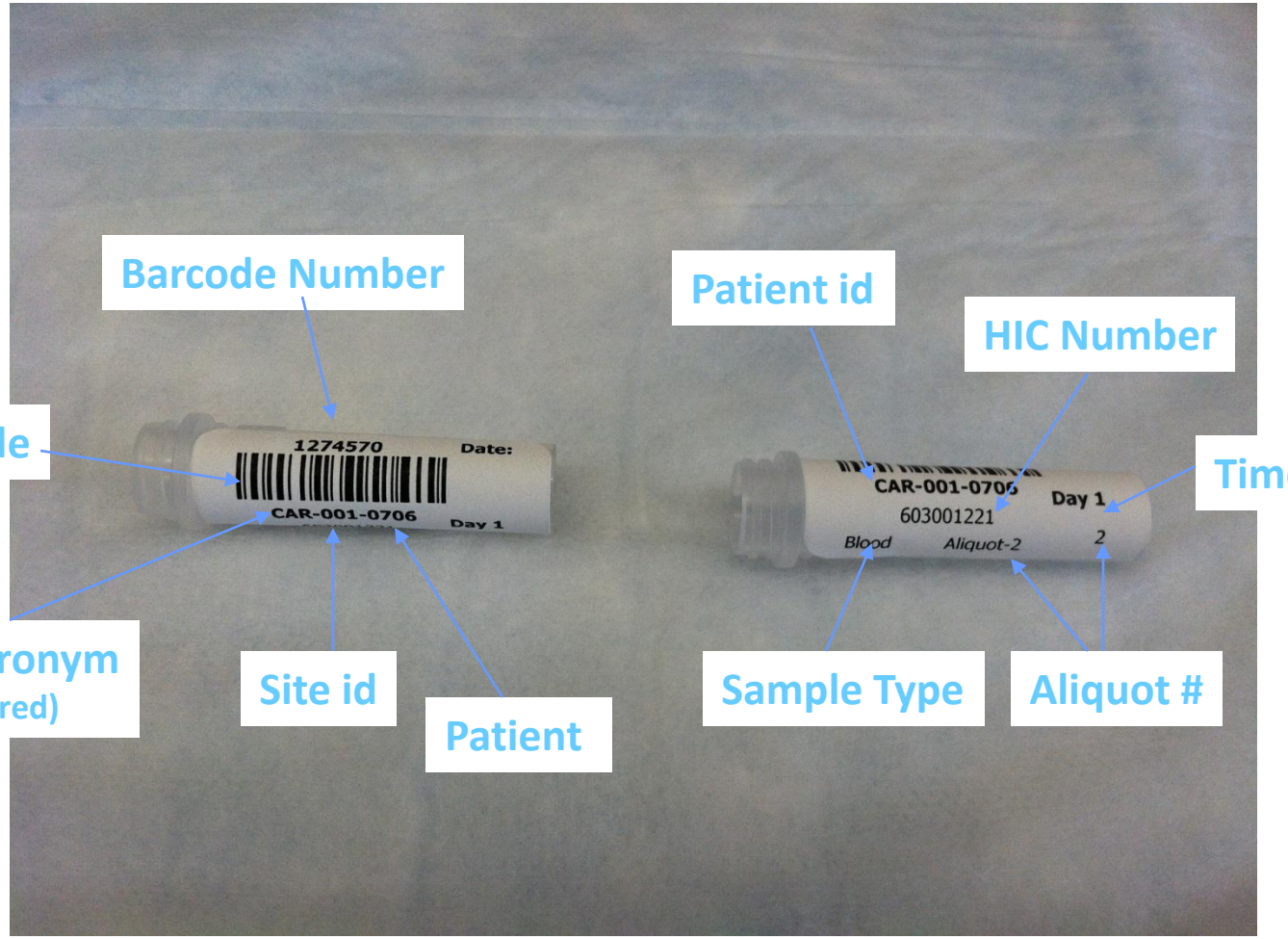
- Scanning Received Specimens
  - Error Recovery for damaged Barcode Labels
- Barcode Label printing
- Integration with Clinical Research Database (TrialDB, REDCap)
  - Real-time bulk data import and export
- Variety of Reports

Typical Freezer



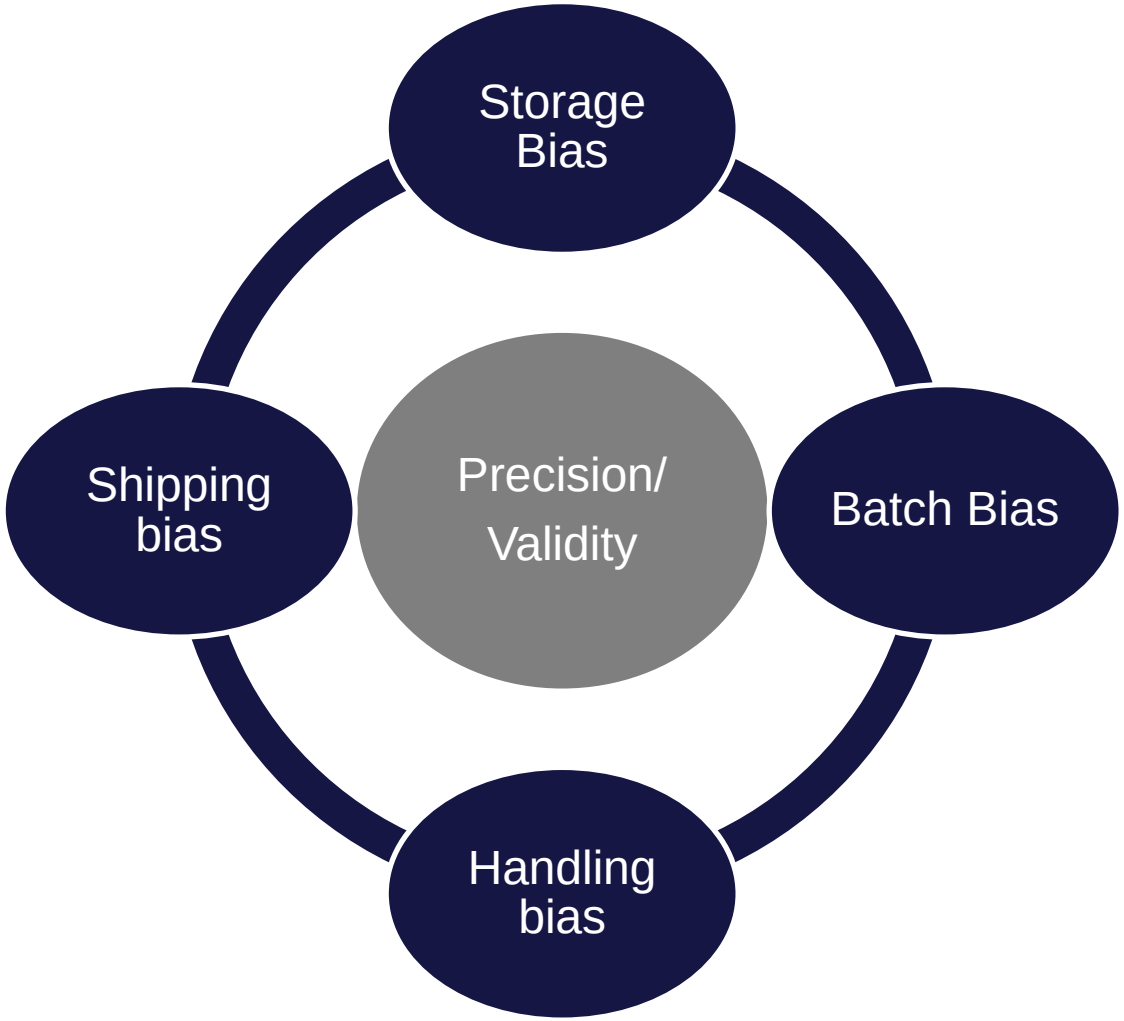
T.R.I.B.E. – A. K. I.

Snapshot of Barcoded Vials



T.R.I.B.E. – A. K. I.

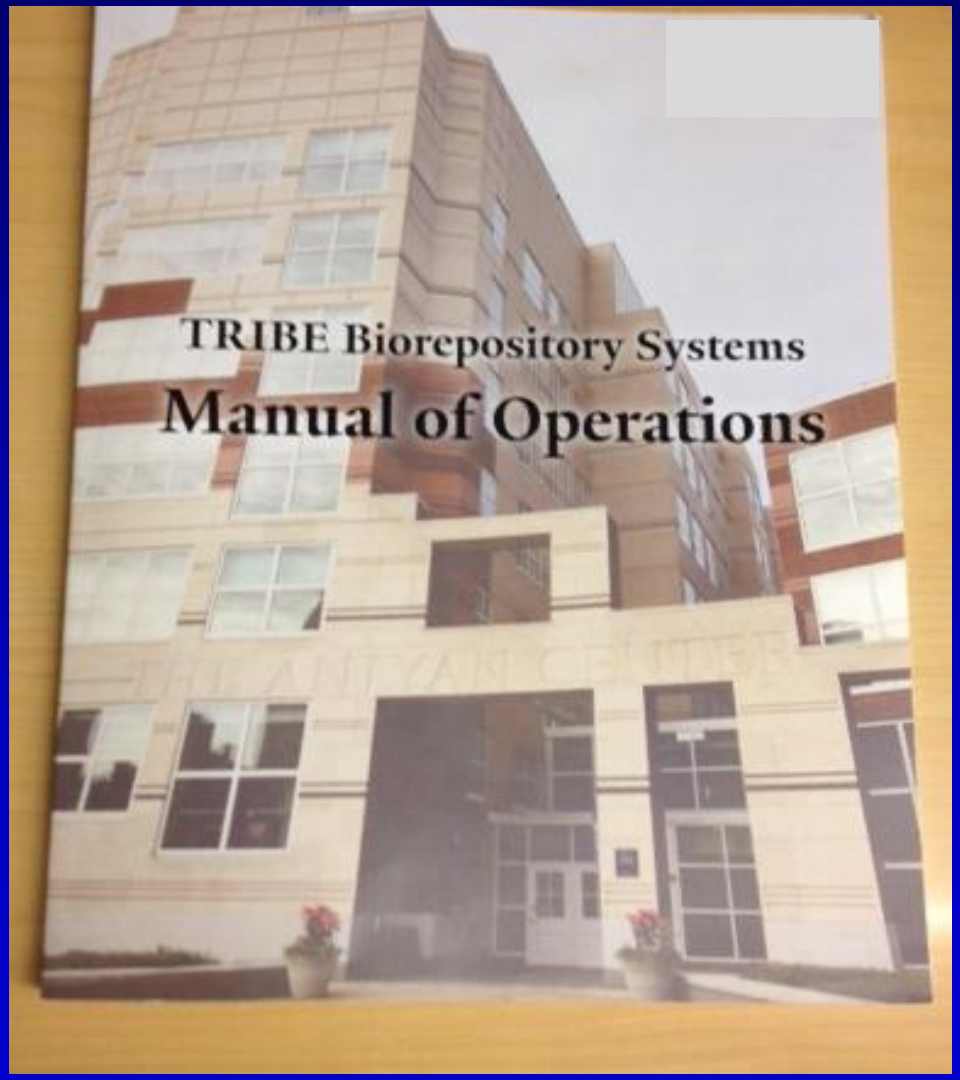
Pre-Analytical Bias With Biomarker Development



“All samples were stored at -80ºC until use.”

- OK… but were specimens *handled equally* in all steps, e.g.,
  - time from blood draw to spin/freeze
  - number of thaw-freeze cycles
  - duration of storage
  - type of blood collection tube (red/purple)
  - time from thawing to assay
  - addition of protease inhibitors
- *Any step is a possible source of fatal bias in a translational research study.*

Development of Protocols and Standardization of Processes



Questions or Collaborations

Chirag.Parikh@jhmi.edu
http://tribe.jhmi.edu/

@KidneydrChirag