Connecting Data Sources with FHIR API's
Protocol/interoperability for cell & gene therapy


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get the data
into the EHR
structured and unstructured
standardized? how?

get it working
the role of clients
the role of servers
sandboxes and more
existing efforts

get it out there
deployment
adoption
how the EHR can help
who else?

three keys to success
Stem Cell Gene Therapy Workflow

- Manufacturing generates a lot of documentation (paper):
  - Manufacturing batch record
  - Lot number documentation
  - All associated quality control testing
  - Certificate of analysis
  - Cell infusion record
- All contained in binders inside the cell processing facility
How this information is helpful

• Cell and Gene Therapy manufacturing processes are characterized by a very high degree of variability, but the target is very specific (e.g. certain number of cells with certain biological properties delivered by a certain day)

• Exact causes of variability are unknown, but are likely to include:
  – Patient-specific factors
    • Age, sex, lifestyle factors, health status, treatment history, genetics, etc.
  – Process-specific factors
    • Biopsy procedure, storage conditions, physician skill, etc.

• Manufacturing process can be adjusted within validated bounds to improve likelihood of delivering product
  – Additional feeds or enriched medium, increased days in culture, re-seeding, etc.

• Information can be used to optimize manufacturing
  – Adapt manufacturing process to projected requirements for particular patient
  – Appropriately schedule manufacturing resources based on probable utilization
  – With QbD effort, determine which factors have significant impact on product manufacturability, quality, and patient outcome
    • Leads to overall process improvements, better product design, and better clinical results

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Use of Cloned Documentation from the Electronic Health Record

- UTMB compliance document [IHOP Policy 6.3.1 Use of Cloned Documentation in the Electronic Health Record]

- (1b) Allergies;
- (1c) Historical procedures and surgeries;
- (1e) Immunizations;
- (1f) Past, family, and/or social history (PFSH); and
- (1g) Dates of scheduled appointments and procedures.

- (2a) Patient;
- (2b) Family member;
- (2d) Review of orders or pharmacy records;
- (2e) Pharmacist; or
- (f2) Physician, nurse or appropriate health care team member.

- The following have a place "to live" in FHIR but you’d need to standardize exactly how to represent them:
  - (1a) Review of systems (ROS);
  - (1d) Developmental history;
  - (2c) Inspection of medication containers;