Alliance Biorepositories and Biospecimen Resource (ABBR)

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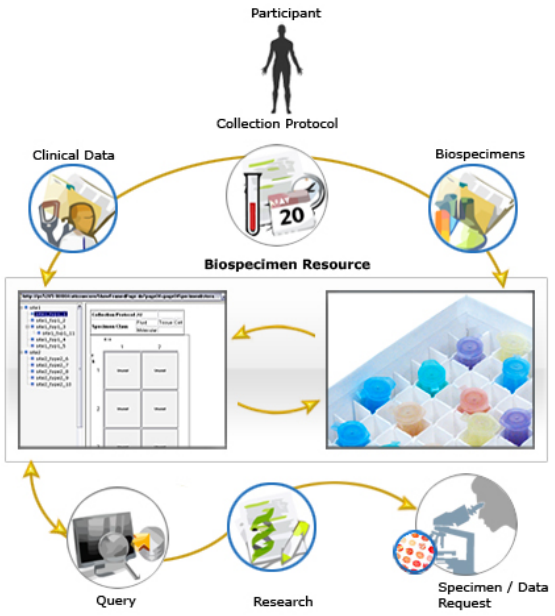
Presentation Objectives

- Become familiar with resources available to collect, process, and distribute biospecimens in the context of Alliance clinical trials.
- Understand the processes and considerations for incorporating biospecimen collection activities into clinical trial design.



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ABBR Aim 1

- Support the collection, processing, and distribution of biospecimens for *integral* and *integrated* correlative science studies in the context of Alliance clinical trials.
  - Funded by an independent U24 funding mechanism and often *other funding sources*.
  - Study design
  - Collection
  - Tracking
  - Processing
  - Storage
  - Distribution

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ABBR Aim 2

- Provide a resource of ‘remnant’ biospecimens for secondary use, correlative science studies.
  - Only after predefined trial studies have been completed.
  - Open access to all investigators.
  - Proposals reviewed by NCI-supervised scientific review committee.
  - Emphasis on studies that require highly annotated biospecimens from uniformly treated clinical trial cohorts.
  - Biorepository services performed on a ‘fee-for-service’ basis.

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ABBR Organization

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Resources and Services

- Study design
- Collection strategies and kits
- Collection site support
- Biospecimen collection / inventory tracking
- Biofluid processing (blood, serum, plasma, urine)
- Tissue processing (histology, stains, TMAs)
- Nucleic acid isolation and QA
- Distribution
- CAP accredited and integrated with clinical CAP laboratories

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Approaches to Biospecimen Collection

- Consider early in the trial design.
- Define significant correlative science aims that will provide a rationale for biospecimen collection.
- Consider the cost / burden of the collection vs. potential scientific value –
  - “Mandatory” vs. “Optional”
  - Clinical tissue block submission
  - Frozen vs. ambient shipping
  - Multiple time point submissions
  - Anticipated accrual

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Approaches to Biospecimen Collection

- Meet with TRP and/or biorepository representatives to discuss collection plan –
  - Which biorepository site will be utilized?
  - Are the logistics feasible for all collection sites?
  - Will additional funding be required for kits or extensive processing?
  - Are there additional opportunities to collect specimens for ‘future use’?
  - Is the trial consent language properly worded?
  - What is the proposed project plan for specimen distribution and utilization?

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Alliance Biospecimen Management System (BioMS)

- Provides a web-based user interface for clinical sites to log, manage, and track biospecimen collections, kit requests, and shipments to Alliance biorepositories.
- Integrates with OPEN registration system.
- Integrates biospecimen inventory across all Alliance sites.
- Provides trial- and site-specific reporting on biospecimen collection and QC.
- Helpdesk support for the application and biobanking in general.

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Conclusion

- Questions?

- Additional Resources –
  - Alliance Policies and Procedures, Chapter 11
  - BioMS web site
  - Alliance biorepository web page
  - NCTN Group Bank web site

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