Technical and Operational Best Practices Overview

State-of-the-Science Biospecimen Handling: Real World Perspective

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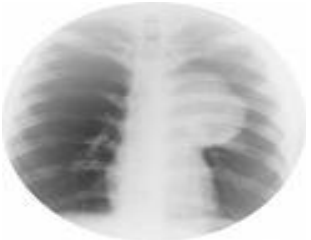
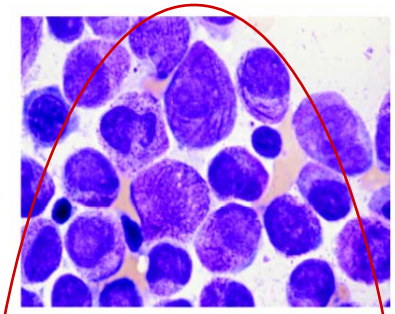
Goal: Personalized medicine leveraging high quality clinical, molecular and family history information

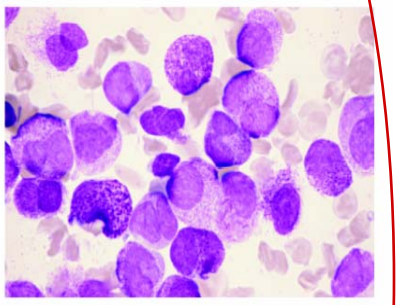
Family history

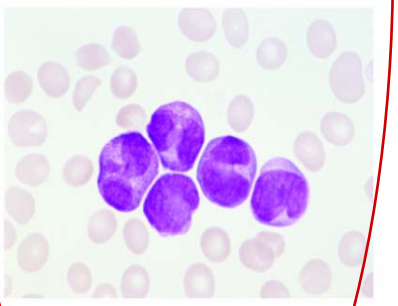
Gender & Age



Disease status



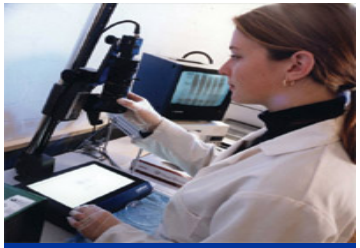




Molecular profiles

Body Weight

Diet & habits

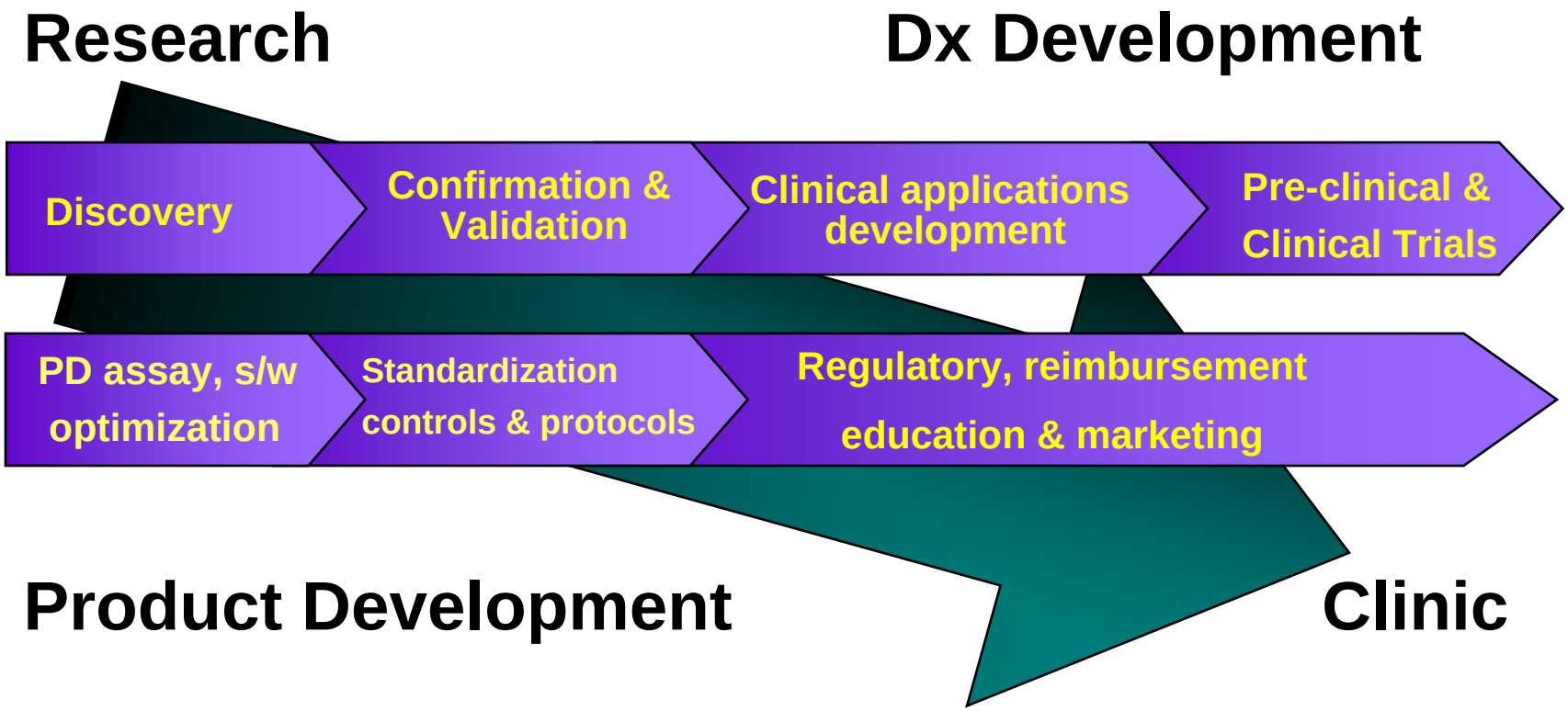


Occupation

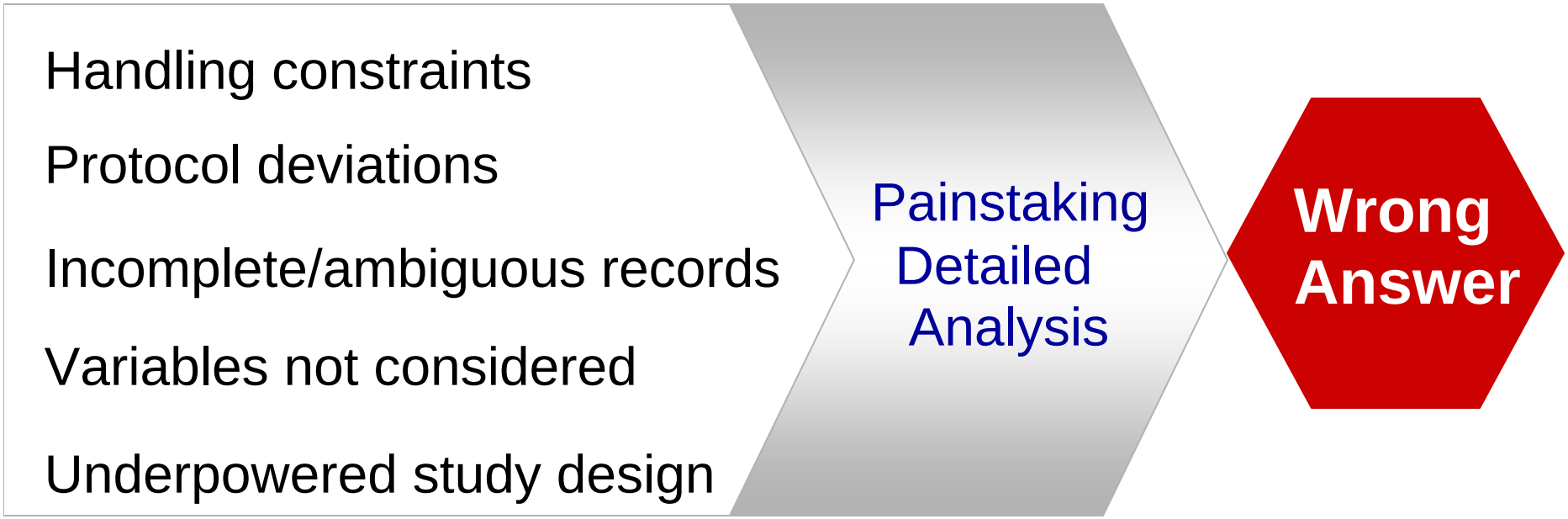
Drug interactions

Patient preferences

Goal: Efficient execution of the critical path
Research and clinical path for drugs and diagnostics is long and costly



Data quality is dependent on managing sources of variability and adequate study power



“Garbage In Garbage Out”

The sample is the greatest source of variability in a well controlled experiment

- Ideally biological variability is the signal above the variability created by sample handling or experimental artifact /noise
- NCI OBBR initiative : Establish meaningful standard operating procedures, agreed-upon metrics and terminology to ensure consistency and standardization for biospecimen resources

Related guidelines
Clinical and Laboratory Standards Institute

- CLSI MM13-A Collection, Transport, Preparation, and Storage of Specimens for Molecular Methods
- CLSI H18-A3 Procedures for the Handling and Processing of Blood Specimens
- CLSI ILA18-A2 Specifications for Immunological Testing for Infectious Diseases
- CLSI MM17-P Verification and Validation of Multiplex Nucleic Acid Assays

www.clsi.org

Other related activities

- International Society for Biological and Environmental Repositories
  - Repository management
  - Best practices development
  - www.isber.org
- Marble Arch Working Group
  - International biobanking initiative
  - Forum for information exchange
  - Harmonization
  - www.oncoreuk.org/pages/MarbleArchWorkingGroup
- Organization of Economic Cooperation and Development
  - www.oecd.org

NCI OBBR Best Practices Overview
B. Technical and Operational Best Practices

- Biospecimen collection, processing, storage, retrieval and dissemination
- Collecting and managing clinical data
- Quality assurance, quality control
- Biosafety
- Biospecimen resource informatics: data management, inventory control and tracking

Biospecimen collection, processing, storage, retrieval and dissemination

- Specifics of handling is dependent on goals/mission of the biospecimen resource however common principles apply to all biospecimen types
  - Selection and handling appropriate for specimen type, research study and fit-for-purpose (e.g. population)
- Minimize impact of collection, processing and storage on tissue quality, minimize time and exposure to factors known to impact quality
  - Establish, implement and benchmark SOPs
  - Establish quality management systems
  - Specimen identification and tracking
  - Data collection documentation
  - Training

Biospecimen collection, processing, storage, retrieval and dissemination

- Store specimen in stabilized state
  - Create aliquots, avoid thawing/refreezing
  - Unambiguous record keeping; processing, quantity, quality and location
  - Back-up power supply, automated security system
- Retrieval and shipping to safeguard quality
  - Confirm assumptions, communicate with recipient
  - Preservation considerations during transit
  - Number and size of samples
  - Temperature management in transit
  - Date of delivery
  - Regulatory considerations, international, national, regional
  - ISBER shipping recommendations
  - OSHA regulations: Identify risks and hazards, take precautions to avoid exposure (CLSI M29-A3)

What is it?

Collecting and managing clinical data

- Appropriate annotation and uniform terminology
  - e.g CaBIG™ common data elements for clinical data
- Sufficient informatics support: Collection, processing, distribution
- Collect and store all relevant clinical and epidemiologic data
  - Comply with participant authorization, privacy rules, human subjects regulations
- Meets appropriate US FDA requirements
  - Code of Federal Regulations
  - As appropriate to IND, IDE applications etc.

- Establish process for confirming/validating clinical data collected
- Track requests for clinical data
- Longitudinal data collection considerations
  - Coded with secure link to participant information
  - Optimized policies and processes for longitudinal data
  - Personnel trained in longitudinal data management issues

Quality assurance, quality control

- Establish Quality Management System or adhere to policies of existing QA/QC program
- SOP manual with detailed policies and procedures
  - Trained personnel
  - Easy reference
  - Document control
  - Review and modification process

Biosafety

- All bio-specimens should be treated as biohazards
- Adhere to key principles of general laboratory safety
- Established protocols for exposure incidents
- Clear policies regarding inclusion of high risk samples
- References to established guidelines
  - CDC, NIH, OSHA
- Training, training, training
- Record keeping and reporting

Biospecimen resource informatics: data management, inventory control and tracking

- Interoperability
- Flexibility to meet changing scientific needs
- Secure, monitored
- Networking capability
  - Share data and tools e.g. NCI Center for Bioinformatics, caBIG™
- System QC, audit logs of access to protected health information
- Adherence to established ethical, legal policy
  - Permissions and roles defined
  - HIPAA
  - Human Subject Regulations, Code of Federal Regulations, e.g. 45 CFR
  - NIST, “Risk Management Guide for Information Technology Systems”

Supports all aspects of biorepository operations

Thank you

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