STANDARDIZATION OF DATA FOR PATHOLOGY RESEARCH

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PROJECT AIM

- **Create a framework for standardization of data used in:**

DESIGN, EXECUTION, ANALYSIS

REGULATORY SUBMISSION

ARCHIVAL

FDA on Data Standards

Data standards enable FDA to ***modernize and streamline the review process****. They also enable more consistent use of analysis tools to better view drug and/or device data and highlight areas of concern. Study data standards describe a standard way to exchange clinical and nonclinical research data between computer systems.*

Tools

CAP Cancer protocols

CAP Cancer Protocols

- 66 CAP Cancer Protocols containing
- 83 eCC Case Summaries
- 13 Biomarker templates
- Utilized in pathology reporting
- Explanatory Notes
- Compilation of standards
  - AJCC 7th ed; WHO Blue Books
- CAP Cancer Protocols Webpage
- Provide cancer reporting required data elements (RDEs)
  - Inclusion of RDEs in pathology report mandated for accreditation by ACoS-CoC & CAP LAP (for resection specimens only)

CAP

CAP Approved

Lung • Biomarkers
LungBiomarkers 1.2.0.0

Lung Biomarker Reporting Template

Template web posting date: December 2015

Completion of the template is the responsibility of the laboratory performing the biomarker testing and/or providing the interpretation. When both testing and interpretation are performed elsewhere (eg, a reference laboratory), synoptic reporting of the results by the laboratory submitting the tissue for testing is also encouraged to ensure that all information is included in the patient's medical record and thus readily available to the treating clinical team.

LUNG

Select a single response unless otherwise indicated.

Note: *Use of this template is optional.*

+ SPECIMEN ADEQUACY

+ Adequacy of Sample for Testing (Note A)
+ ___ Adequate
  + Estimated tumor cellularity (area used for testing): ____%
+ ___ Suboptimal (explain): _____

Note: If "Adequate" not selected, please refer to original laboratory report for explanation.

+ SPECIMEN TYPE
+ ___ Untreated diagnostic specimen
+ ___ Relapse specimen (after treatment; specify: _____)*

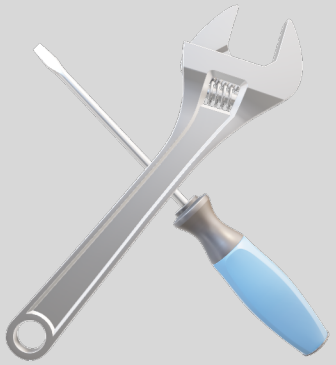
**When data is available, specify treatment type. This is most relevant to targeted inhibitors associated with specific genomic changes conferring treatment resistance (especially erlotinib, gefitinib, and other EGFR tyrosine kinase inhibitors).*

+ RESULTS

+ *EGFR* Mutational Analysis (Note B)

Courtesy Kerren Hulkower, PhD, 2016

Tools – Existing Medical Industry Standards



- CDISC – Pharma and Medical Device data standards
  - A standards developing organization (SDO) dealing with medical research data linked with healthcare
  - Widely used for FDA submission
- HL7
- Others

Key elements

- Identify existing variables in the CAP cancer protocols
- Create controlled terminologies - **set of codelists and valid values used in the cancer protocols**
- Create a data dictionary that identifies and defines each variable identified
- Develop a machine-readable data structure
- Create standard computer programs to derive standard data from different databases

Pros for patients, clinical, R&D, and regulatory

- Data standards will create very robust interoperability and improve clinical, R &D and regulatory data sharing ultimately benefitting patients

Deliverable and timeline

- Deliverables
- Identify existing CAP cancer variables – **6 months**
- Create controlled terminologies - **- 6 months**
- Create a data dictionary **- 6 months**
- Develop a machine-readable data structure – 3 months
- Create standard computer programs -3 months