PP01 Metrics for laboratory test panels information in SDTM data

Sergiy Sirichenko, Michael Beers, Pinnacle 21

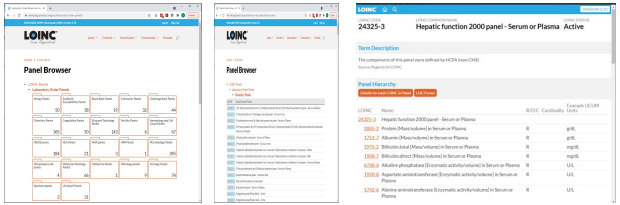
Introduction

Usually, a single observation is not enough for making clinical diagnosis. For example, assessment of blood pressure consists of two tests for systolic and diastolic blood pressure. The same is true for lab data. Laboratory test panels are a concept heavily utilized by medical professionals. However, it's not covered by **CDISC** standards.

In the health care industry, **ICD** claims coding system includes special codes for laboratory panels defined as "*a package of tests that are often ordered together*". There is a disclaimer, that "*panels were developed for coding purposes only and should not be interpreted as clinical parameters*".

LOINC has the most advanced coding for lab tests panels. "*We use the word "panel" to mean collector terms that contain links to an enumerated set of discrete child elements*". It includes several levels of grouped information. For example,

LOINC Panels -> Laboratory Order Panels -> Chemistry Panels -> Hepatic function 2000 panel



HL7 FHIR has special element for Diagnostic Report Names

Methodology and results

We utilized the same metrics as for CT research already presented at PhUSE US Connect 2021 [DS08].

2488 studies with Lab data which include the following variables:

- LBCAT 2478 (99.60%) studies
- LBSCAT 995 (40.0%)
- LBSPEC 2230 (89.6%)
- LBMETHOD 1235 (49.6%)
- LBLOINC 75 (3.0%) - 17 studies include only a single term; another 25 include only 5 or less terms

LBCAT

1902 unique terms across 2478 studies

10 most common terms in LBCAT

Term	# of studies	% of studies
HEMATOLOGY	2241	90.1%
URINALYSIS	1988	79.9%
CHEMISTRY	1872	75.2%
COAGULATION	925	37.2%
SEROLOGY	743	29.9%
IMMUNOLOGY	580	23.3%
MICROBIOLOGY	301	12.1%
PREGNANCY	296	11.9%
VIROLOGY	290	11.7%
ENDOCRINOLOGY	258	10.4%

There are 30+ additional terms for Chemistry which increase 75% to 95+%

Example:

Term	# of studies	% of studies
CHEMISTRY	1872	75.2%
CLINICAL CHEMISTRY	161	6.5%
GENERAL CHEMISTRY	69	2.8%
OTHER CHEMISTRY TESTING	63	2.5%
BLOOD CHEMISTRY	47	1.9%
Chemistry	36	1.4%
URINE CHEMISTRY	30	1.2%
SERUM CHEMISTRY	21	0.8%
SPECIAL CHEMISTRY	18	0.7%
CHEMISTRY 1	8	0.3%

LBSCAT

1032 unique terms across 995 studies

10 most common terms in LBSCAT

Term	# of studies	% of studies
ELECTROLYTES	151	6.1%
PARTIAL THROMBOPLASTIN TIME	119	4.8%
LIVER FUNCTION	101	4.1%
COAGULATION	93	3.7%
KIDNEY FUNCTION	92	3.7%
DIFFERENTIAL	86	3.5%
PROTEINS	84	3.4%
DIPSTICK	80	3.2%
PREGNANCY	76	3.1%
HORMONE	64	2.6%

LBSPEC

264 unique terms across 2230 studies

5 most common terms in LBSPEC

Term	# of studies	% of studies
URINE	2002	80.5%
BLOOD	1880	75.6%
SERUM	1732	69.6%
PLASMA	1157	46.5%
STOOL	304	12.2%

LBMETHOD

753 unique terms across 1235 studies

5 most common terms in LBSPEC

Term	# of studies	% of studies
DIPSTICK	369	14.8%
CALCULATION	277	11.1%
MICROSCOPY	265	10.7%
QUALITATIVE ASSESSMENT	216	8.7%
ELISA	195	7.8%

Summary

Lab test panels information is not standardized in submission data.

Sponsors utilize LBCAT and LBSCAT variables for this type of information. In most studies the same terms such as 'HEMATOLOGY' or 'CHEMISTRY' are used despite the absence of formal standard CDISC SDTM Terminology. LBSCAT variable is often utilized to provide additional granularity of lab panel info similar to Panels in LOINC coding system.

Due to its flat structure, the SDTM model does not work well for lab test panels. For example, the same test may be a part of several different panels. In the LOINC system, definition of panels includes references to different test observations. It's challenging to do the same in SDTM data. LOINC coding information in SDTM data may help, but it is still in its initial stage of adoption by the industry.

CDISC and regulatory agencies may consider the creation of Standard Terminology for Lab Category and Subcategory variables according to current implementation by the industry.

Lab test results represent a large portion of study data. Standardization of lab panels info helps with automation of lab data processing and review. Analysis of industry implementation metrics may help with identification of potential problems and finding potential approaches for their resolution.