Lab Interpreted Result Concept Overview

Purpose

We seek support for the standardized transfer of Lab Interpreted Results between systems. This information is critical to certain forms of pharmacogenomics clinical decision support (CDS). There are situations where CDS rules could use this information to alert a clinician if they order a drug or a drug dose that is contraindicated by the patient's genetic profile.

The goal of this document is to specify the required components of the Lab Interpreted Result concept. Our goal is to enable standards bodies to consider incorporating this concept so that health information technology vendors can develop interfaces needed to transfer these data across organizational boundaries. The need for a standard mechanism for representing genomic variation is acknowledged to also be important but is beyond the scope of this document.

Concept Overview

The types of Lab Interpreted Results that we seek support for at this stage are:

- Metabolic Lab Interpreted Results
  To be used in situations where a test assesses one or more genes for metabolism associated pharmacogenomics effects
- Sensitivity Lab Interpreted Results
  To be used in situations where a test assesses one or more genes that may convey adverse drug sensitivity

Additional types of Lab Interpreted Results will need to be specified in the future to account for other types of genetic test results, including other types of Pharmacogenomic tests.

Each test report may contain multiple Lab Interpreted Results.

We envision laboratories "signing out" these Lab Interpreted Results through the reporting process. Clinicians/Providers will be responsible for applying the Lab Interpreted Results to specific patient situations and determining the effect the results should have on drug prescribing.

Metabolic Lab Interpreted Result Components

Each Metabolic Lab Interpreted Result must contain these two fields:

- Gene: The gene that was tested – in HGVS nomenclature
- Metabolizer Status: Indication of the effect of any variants on the gene's ability to metabolize drugs. CPIC and ClinGen are working to develop an ontology for this field.

Sensitivity Lab Interpreted Result Components

Each Sensitivity Lab Interpreted Result must contain these three fields:

- Gene: The gene that was tested – in HGVS nomenclature
- Drug: The drug potentially affected by variants in this gene – in RxNorm
- Sensitivity Status: Indication of the effect of any variants on the patients' sensitivity to the drug. CPIC and ClinGen are working to develop an ontology for this field.