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|  | SHIELD Project Status Report | Medieval Armor outline |  |
| Project Name: AST IVD REporting | | | | |
| Initiative Summary | | | | |
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| Submission Date | Project Name | Submitted BY (SOurce) include email |
| 28Mar23 | AST IVD Reporting: Immunoassay interpretation | Xavier Gansel (Biomerieux) |

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| Summary of Problem/Issue/Need |
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Description of the Project/Issue(s)/Needs: IVD vendor mapping guidance of Antimicrobial Susceptibility Values in LIVD/LIDR, in LIS/EHRs/PH labs, and transmission to other LIS/EHR/PH, and use for RWD/RWE, surveillance, etc. (list all). Identification of coding, messaging gaps, and training/education needed. Issue: There are two different ways laboratories are modeling these results in their LIS/EHR and transferring/messaging to other information systems.

For Immunoassay interpretation results, with the following qualitative result values, recommended mapping is to SNOMED CT Qualifier Value codes. The Immunoassay results will be mapped to LOINC in the US. (May wish to include a list of immunoassays mapped to LOINC, and these values to SCT in LIVD if available)

Table

Description automatically generated

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| ITEM Overview |
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| Item | Details | SC Comments |
| **Types of Lab Data involved** | **Result values** |  |
| **Are data discrete?** | **Yes from IVD device and in LIS, EHR, PH system, etc** |  |
| **Existing standards? (Describe coding, messaging, etc.)** | **Use existing codes from SCT Qualifier hierarchy. IVD provides mapped result values in LIVD. LIS functionality to map to SCT qualifier values** |  |
| **---If no, gaps to be filled?** | **Confirm LIS, PH IS, and EHRs and other downstream systems all support mapping this item to SCT qualifier codes.**  **(May be out of scope for this, but APLIS systems may or may not have functionality to support for pathology result values, especially if immunoassay is mapped in LIS one way and used in APLIS structured/mapped differently. Any overlap?)** |  |
| **Exchangeable data? How?** | **HL7 V2 format: Value and mapped code in OBX5**  **FHIR Observation:**  **FHIR Diagnostic Report:**  **CDA:** |  |
| **---If no, gaps to be filled?** | **Confirm FHIR functionality is available** |  |
| **Where Occurs in Lab Workflow(s) (IVD, LIS, EHR, PH, RWE, etc.)** | **IVD, LIS, EHR, RWE** |  |
| **Who/What Impacted? (lab area, clinicians, PH, patients, labs, IVD vendors)** | **Microbiology for this use case, but also Chemistry, and Immunology, Serology for immunoassays and qualitative result values from hematology, blood bank, Pathology** |  |
| **Scope of Impact (Broad, Narrow, Global, Regional, etc.)** | **Broad. Global.** |  |
| **Who/What working upon? (e.g. SHIELD WG, external entity, none)** | **Looking for SHIELD Steering Committee Approval. For this item, a WG isn’t expected, but for related coding needs. Looking for required functionality in all information systems to send and receive. In USCDI, but looking for all information systems to have certification functionality to support. (additional CLIA needs/alignment/updates?, ONC/FDA/CDC regulatory/policy needs?)** |  |
| **Other Info to Consider (links, papers, etc.)** | **Links to papers, posters, analysis? List CLSI, EUCAST guidelines, etc.?** |  |
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| Proposed Solution(S)/Desired Outcomes |
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| ITEM (List Each) | Solution Description | ASSIGNED TO | DATE |
| **SC approval of mapping standard** |  |  |  |
| **IVD LIVD map creation** |  |  |  |
| **Policy/regulatory updates?** | **FDA IVD requirements? ONC LIS/EHR requirements? CDC/PH requirements** |  |  |
| **Marketing/education/implementation plan** |  |  |  |
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| Steering COmmittee Decisions |
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| task | Vote? | DATE | Assigned TO | notes |
| **Item Approved, Prioritized, or Parking Lot?** |  |  | **WG? External?** | **Indicate Review/Approval by SC and to whom assigned** |
| **More Info Needed?** |  |  |  |  |
| **Expected Timeline (start & end)** |  |  |  |  |
| **SC member(s) lead/liaison** |  |  |  |  |
| **Other SC members on task** |  |  |  |  |

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| Project Overview |
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| task | Due date | Assigned TO | notes |
| **SC approval** |  | **Co chairs** |  |
| **LIVD maps** |  | **IVD vendors** |  |
| **Policy/regulatory updates** |  | **agencies** |  |
| **Marketing/education? Implementation plan** |  | **SHIELD WG?** |  |
| **List other anticipated tasks** |  |  |  |

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| CONCLUSIONS/RECOMMENDATIONS |
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