History of LB

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Global Data Standards

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14-Mar-2023
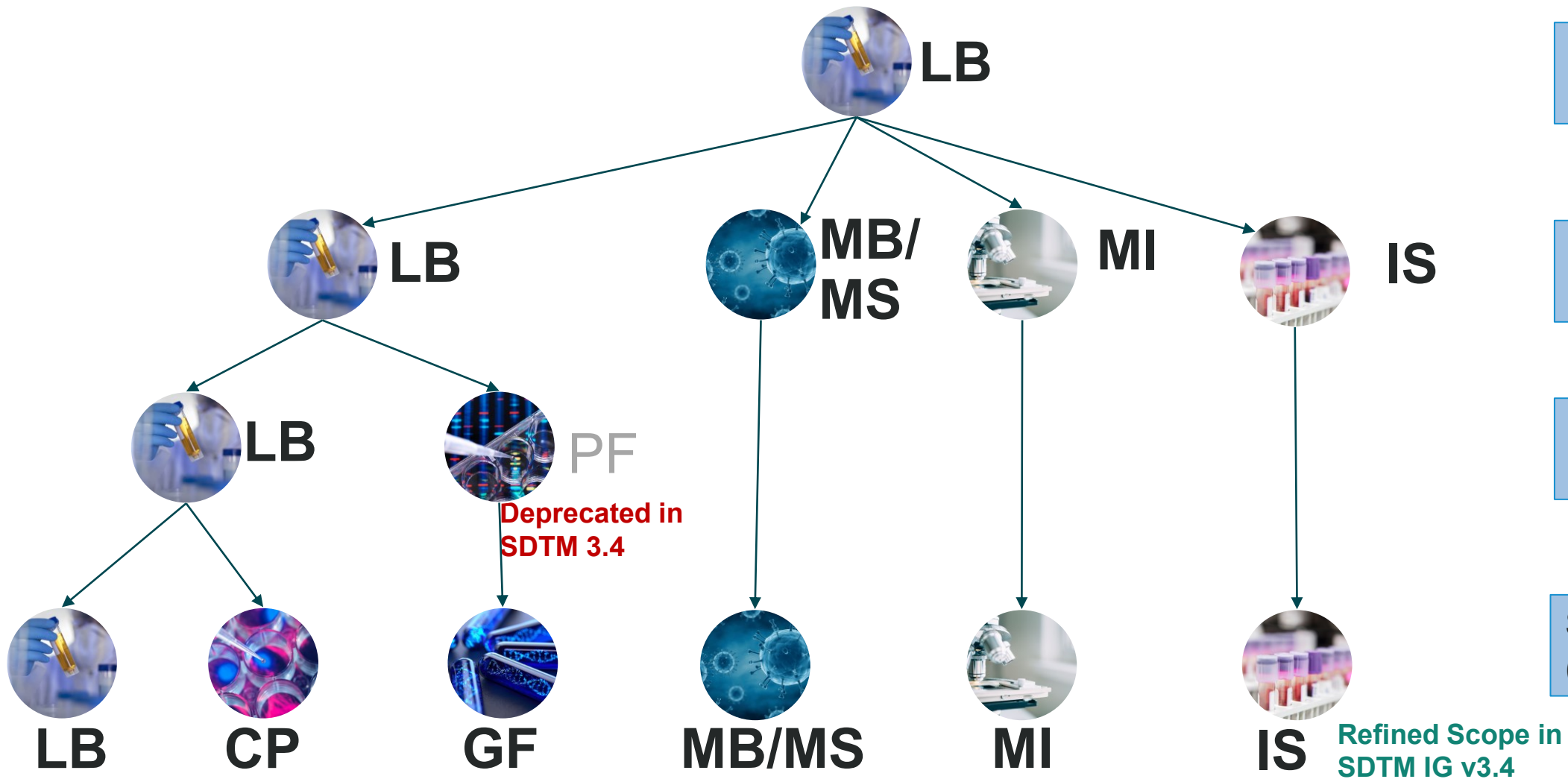
Evolution of the Domains

> **From one big container for all lab data to distinct domains based on data type**

- IS: Immunogenicity Specimen Assessments
  - Previous: assessments that describe whether a **therapy** provoked/caused/induced an immune response
  - v3.4: immune response upon an **antigen** stimulation or encounter (incl. Anti-Drug-Antibody Data)
- MI: Microscopic Findings
- MB: Microbiology Specimen
  - MS: Microbiology Susceptibility
- GF: Genomics Findings
  - PF: Deprecated and replaced by GF Domain in SDTM IG v3.4
- CP: Cell Phenotyping Findings
- LB: Laboratory Test Results
- BS: Biospecimen Findings (Findings related to specimen handling and specimen characteristics for all lab data)

Evolution of Variables

➢ Reducing the need for variables in SUPP--

➢ Test (--TEST/--TESTCD): No longer overloaded with information

- **Further details of the test:** Test Detail (--TSTDTL), Test Condition (--TSTCND), Test Operational Objective (--TSTOPO)
- **Further details of the result:** Result Type (--RESTYP); Result Scale (--RESSCL)
- **Further details of the method:** Method Sensitivity (--TMTHSN); Analysis Method (--ANMETH)
- **Further Timing Information**: Point in Time Flag (--PTFL); Planned Duration (--PDUR)
- **Specific Variables for the data type:**
  - Binding Agent (--BDAGNT), Marker String (--MRKSTR), Gate Name (--GATE), .., for CP
  - Genome Reference (GFGENREF), Genetic Location (GFGENLOC), …, for GF
- Available for all domains (mandatory only for LB): Loinc Code (--LOINC)

Wrap Up

– Different domains and specific variables developed over time

– Lab data type determines where the data are stored and with which variables

– Data Collection and Data Transfer Specs from Vendors need to collect the necessary information to explain the data