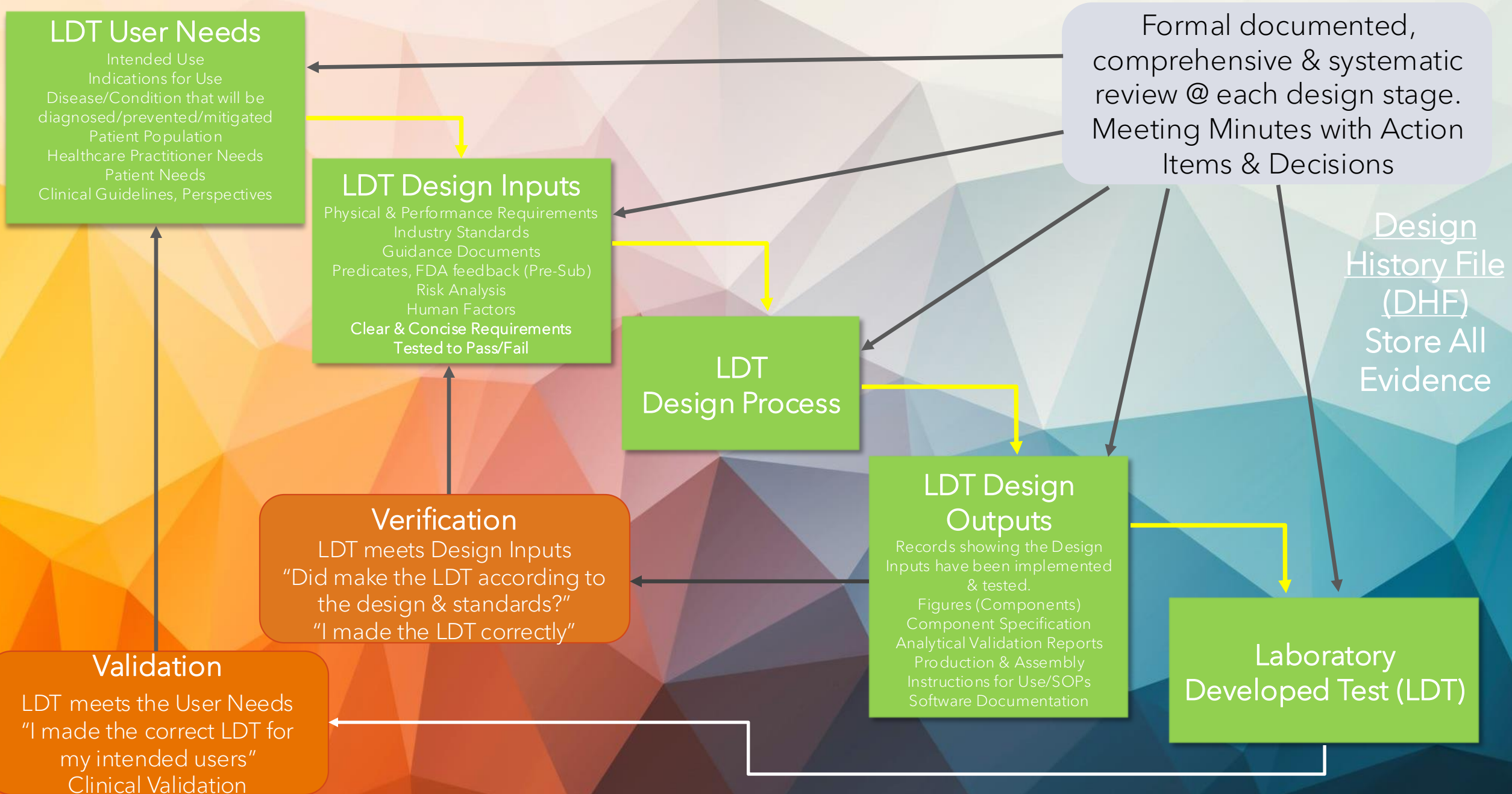


Design Control for Labs: Ensure LDT meets User Needs, Specified Requirements & Intended Use



Summary of Required Documentation

- Intended Use & Indications For Use
- Design & Development Plan
 - Overall laboratory approach to LDT design & development*
 - Timelines, Milestones & Laboratory Team Responsibilities for each LDT*
- User Needs Documented (Clinical perspectives, clinical guidelines, etc.)
- Design Inputs (LDT Requirements) Documented
- Design Outputs Documentation
- Risk Management File
 - Risk Management Plan & Risk Assessment throughout LDT Design & Development Process*
 - Potential LDT Failure Modes, Risk Analysis, Risk Mitigation, & Risk/Benefit Analysis*
- LDT Verification (e.g., analytical validation testing) & Validation (e.g., clinical validation) Plans/Protocols & Reports
- Traceability Matrix > map design inputs to design outputs, verification (analytical) testing & validation (clinical) testing
- Formal Design Review Documentation (Decisions, Issues, Action Items, & Outcomes > Personnel to Review Design)
- Change Control Records (any LDT changes after initial approval & through the LDT lifecycle)
- Standard Operating Procedures (SOPs) & Work Instructions (WIs)
- LDT Labeling & Instructions for Use
- Training Records showing personnel are trained on design control procedures, LDT use & quality standards

“If it's not documented, it's not done”