Adoption Story from a Biopharmaceutical Organization

Case Study:
Digital Data Flow Journey

TransCelerate BIOPHARMA INC.

Clinical Development

Leveraging Digital Data Flow to accelerate Clinical Development through a common data model on a technology platform

Traditional

Study Resource Approval

Protocol Approval

FPFV

Design Time

- Protocol Design Workspace
- Optimize Study
- Finalize Study
- Author Protocol

Operationalize

- Setup Lab Vendor
- Site Contracts
- Build eDC
- Author Informed Consent

Key activities occur in series, and are largely manually-driven and based on human review of documents, with no single source of truth

Next Gen (DDF)

Study Resource Approval

Protocol Approval

FPFV

Design Time

- Protocol Design Workspace
- Standard Driven Study Builder
- Data Platform
  - Study Design Repository

Operationalize

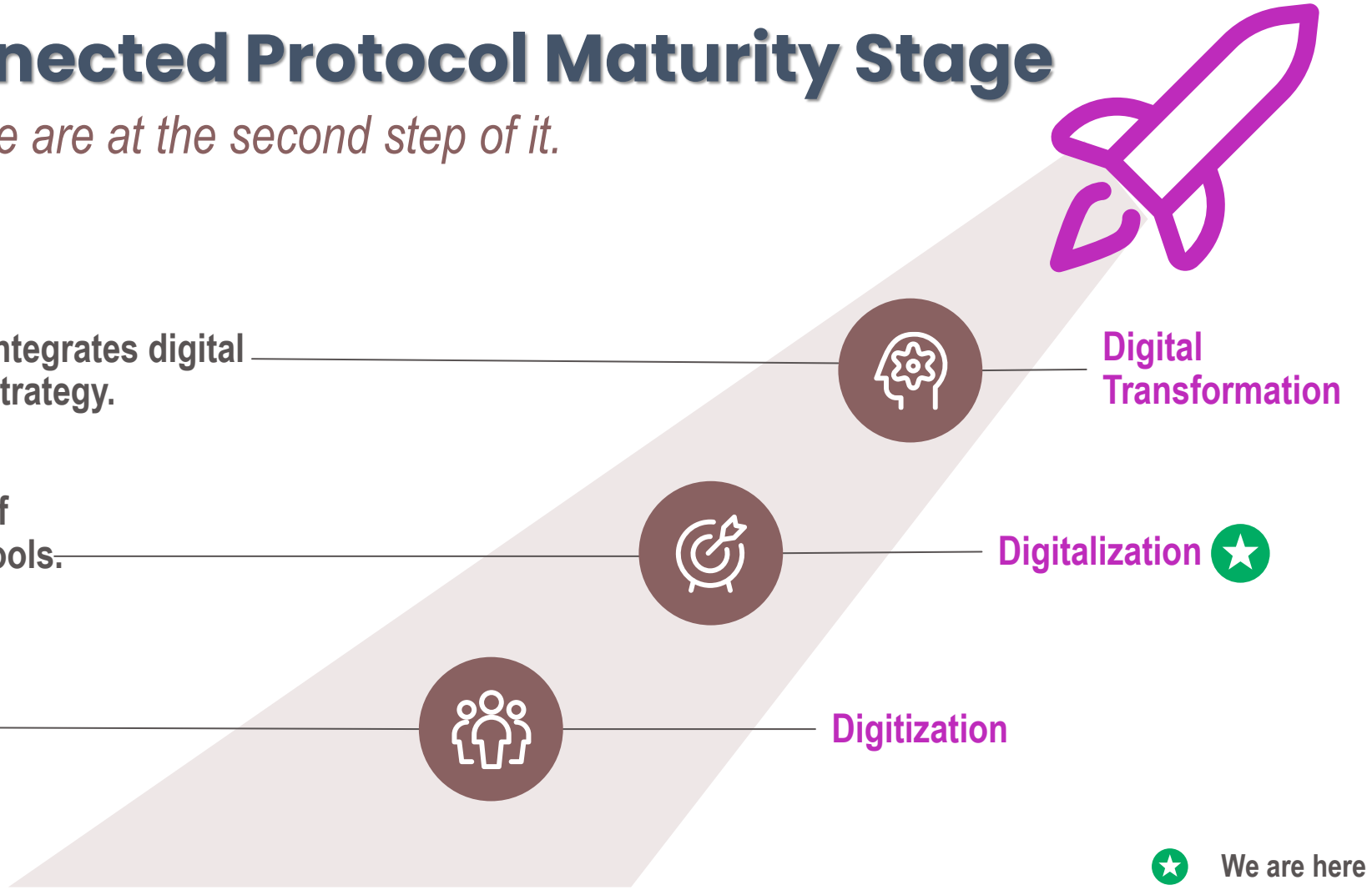
Orchestrate Early Clinical Trial Execution

Using a Digital Data Flow Solution

Many activities can now occur in parallel, with reference to a single digital protocol, enabling automation to be introduced to replace low-value manual tasks

Our Digitally-Connected Protocol Maturity Stage

Three broader maturity level. We are at the second step of it.



Achieve a holistic transformation that integrates digital protocols into the core organizational strategy.

Digital Transformation

Enhance efficiency and effectiveness of protocol development through digital tools.

Digitalization

Establish a digital foundation by converting paper-based protocols into digital documents

Digitization

We are here

Success So far …

Digital Data Flow has evolved, and is starting to enable automation clinical operations, helping kickstart clinical activities ahead of time

Early Insights

Deliver actionable insights ~2 months earlier in the trial lifecycle**

Specimen Generation Plan

3 to 4 weeks faster study set-up through digitized SOA & Specimen Plan automation

Lab Contracts Generation

Contract negotiation initiated earlier in trial lifecycle

External Data Contracts

~17k hours annually saved by streamlining activities in transfer agreement generation, data review and approvals E2E

Site Contracts Negotiation

Contract negotiation initiated earlier in trial lifecycle accelerating US site contracting for RCO* by 6 to 8 weeks (~50% reduction)

* RCO – Regional Clinical Operations
** Contingent upon the capabilities adopted

Specimen Management Plan Automation

Automation

- ✓ Specimen Planning is Embedded in the SOA
- ✓ Standards-Driven Plan Generation
- ✓ Specimen Testing and Logistics Requirements feed Setup activities

Impact

- Faster, more consistent Plan generation, **optimized by Visit**
- Digitized Plan captures detail and variability like never before
- Quicker lab readiness through customized digital outputs

Site Budget Negotiation Reports

Automation

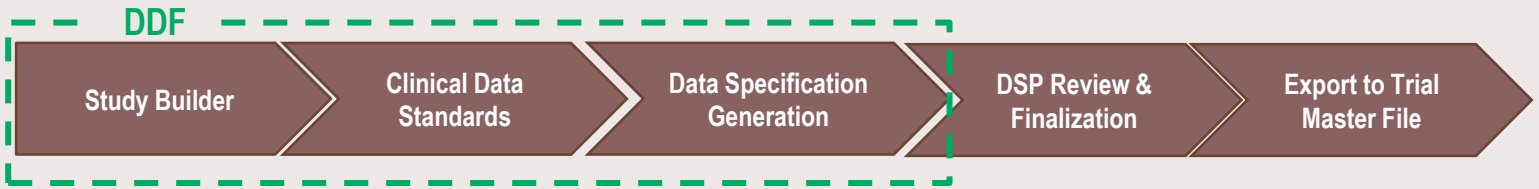
- ✓ All lab-related inputs (test names, frequency, volume) consolidated into one automated, exportable format
- ✓ Accelerates site-ready negotiation packages aligned with protocol and lab plans

Impact

- Accelerates US Site Contracting for RCO
- Accelerates Site Negotiation process
- Improves speed and reduce transcription errors with automated report

External Data Contracts Tracking System

Automation



- ✓ Accelerate DSP creation with digitized study data and clinical data standards, ensuring faster, higher-quality, and consistent data
- ✓ Seamless user experience, allowing easy drafting, finalization, and storage of study Data Specification Packages (DSP) for External Data Acquisition team access

Impact

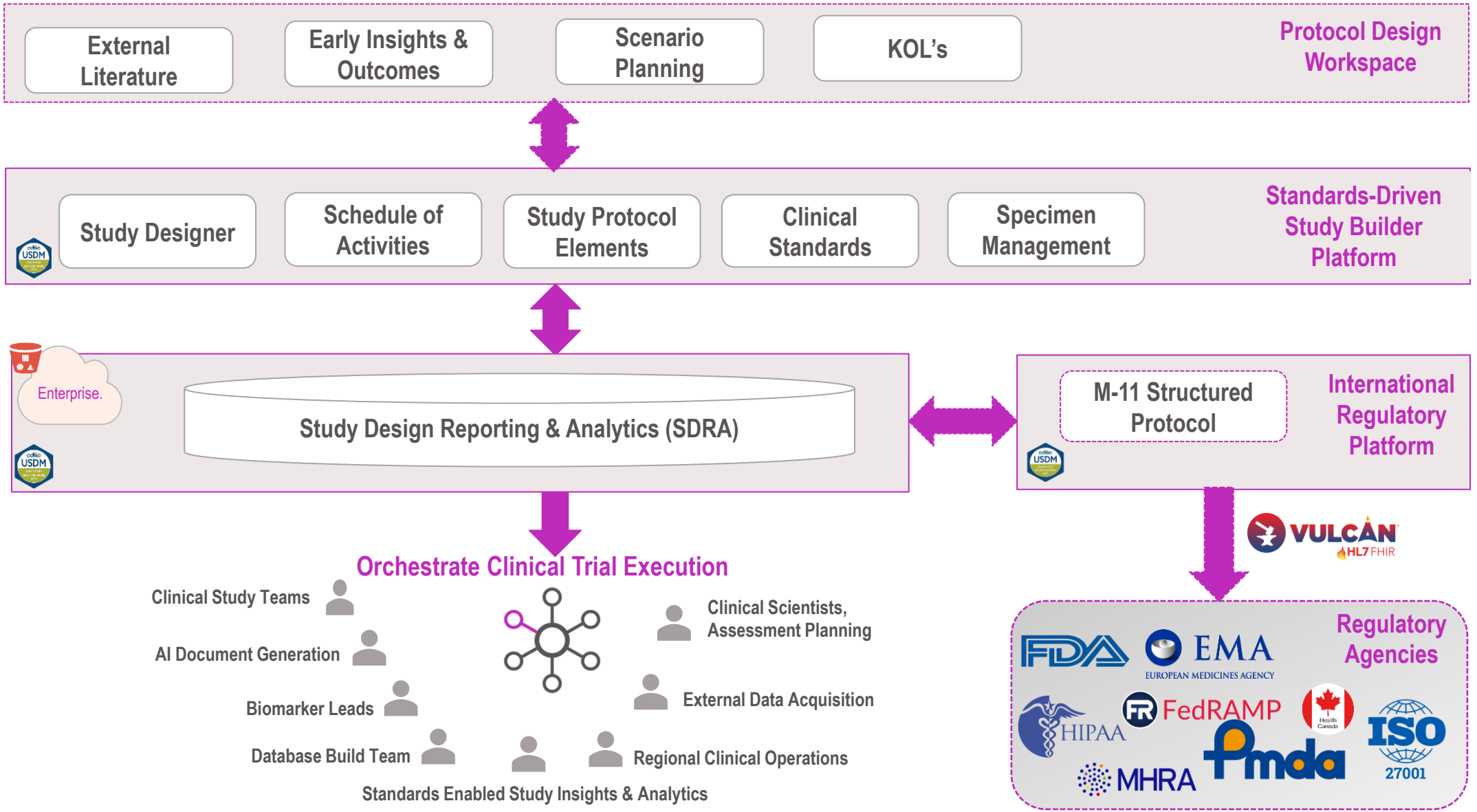
The External Data Acquisition Portal will provide team with ~1000 pre-filled **Data Specification Package(DSP)** annually, resulting in cost savings and efficient vendor engagements

Reduced Manual Work

Higher Consistency Across Data Specification Package

Automated Data Specification Package Creation

Conceptual Overview



Future State

Standards Driven Study Design

Automation

- ✓ Standard design elements such as phase TA, indication, population, and cohort reduces variability and ambiguity in data interpretation
- ✓ Standard Schedule of Activity elements such as visit, epoch, activity, procedure, and biomedical concepts drives downstream automation
- ✓ Data collection elements such as crf name, variable name, and code lists reduces variability and ambiguity

Impact

- Improved Data Quality and Consistency ensuring uniformity across sites/studies
- Faster Study Start-Up and Execution via enhanced data integration & reuse
- Regulatory Compliance and Readiness by minimizing delays/rejections

Digital Protocol Transformation Challenges