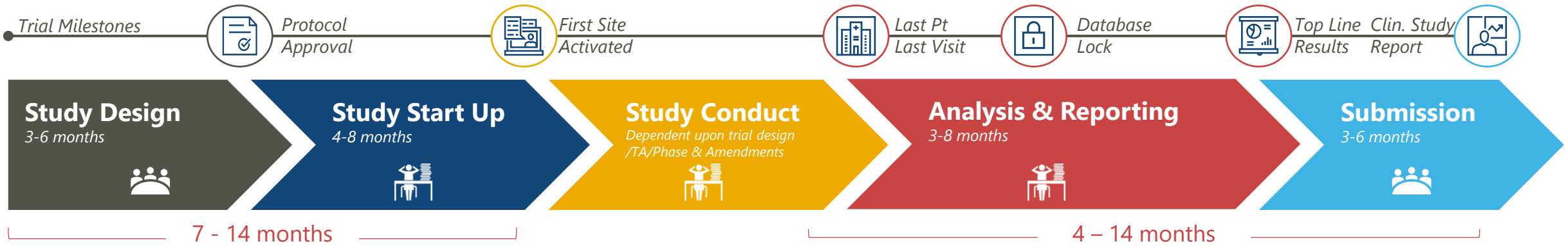
CDISC 360i: Transforming Clinical Research Through Standards-Driven Automation


There's nothing efficient
about innovation.
Simon Sinek
quotefancy

As biopharma pivots from research-oriented to competitive development models, cycle time is the new currency



The current trial lifecycle is linear resulting in sub-optimization of critical path activities. Key limitations under the current-state include:

Labor-Intensive Study Design & Start-up

Manual authoring and multiple review cycles of 70+ different study start-up artifacts

"~30% of participant and site burden is associated with non-essential procedures supporting core endpoints."[1]

Amendments

Amendments are time consuming costly, often result in system configuration updates and reversions

"Average of 4 amendments per trial and implementation cost of 500K per amendment"[2]

Trial Data Bottlenecks

Lack of data standardization requires significant effort & cycle time to transform data

"Each phase III protocol gathers, on average, 5.9 million datapoints, up 67% since 2020."[4]

Late SAP Finalization

Analysis requirements defined late in the trial life cycle complicate application of risk-based approaches

"1 day delay in asset development can result in $600K - $8M loss of revenue per day."[2]

Labor Intensive Analysis & Reporting

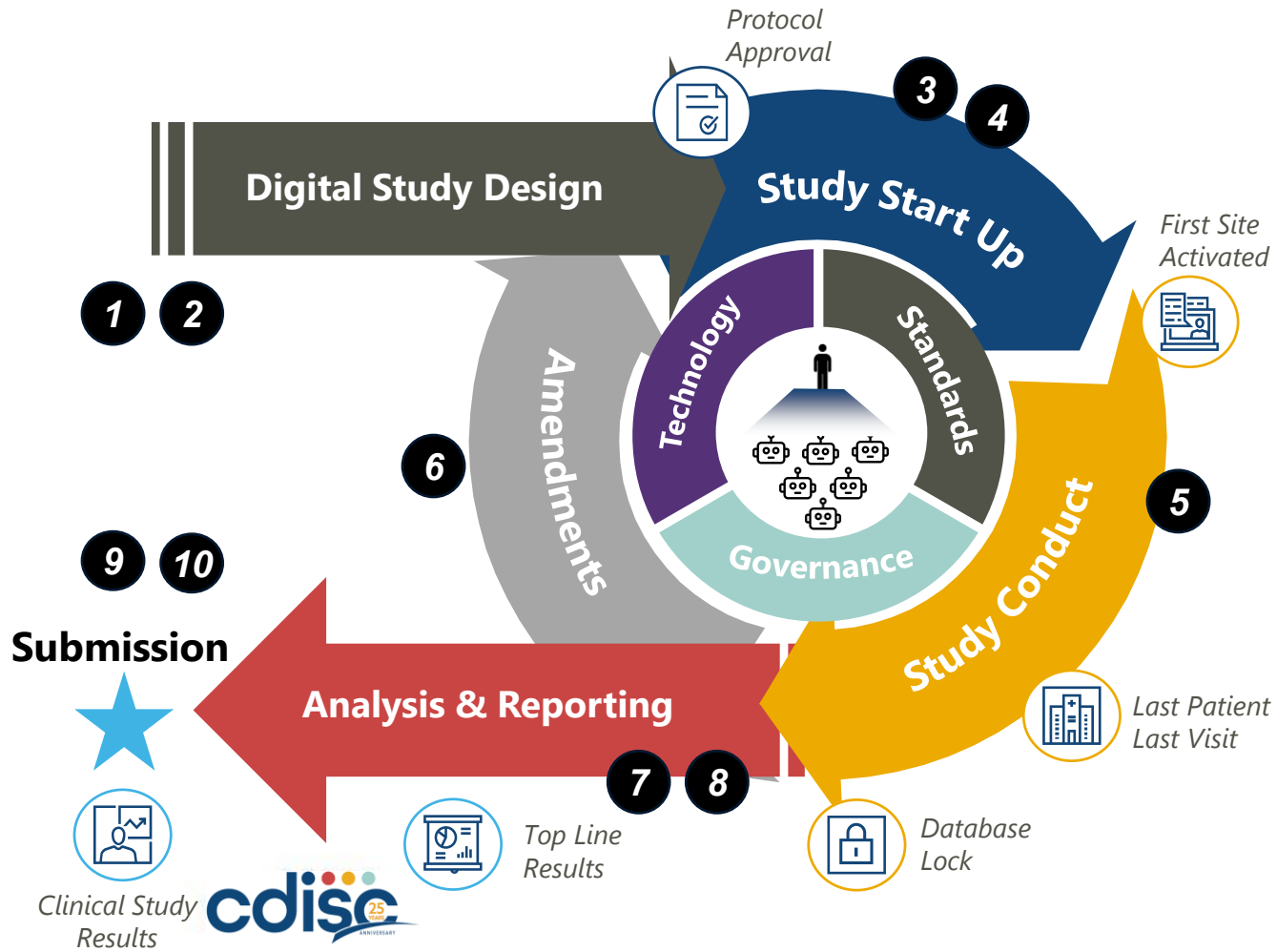
Authoring and review cycles of the CSR dependent upon full analysis & data

"25% of all data collected in a trial is not used in the CSR."[5]

Citations: 1, 2, 3 - Insights informing strategies for optimizing the collection of clinical trial data, Ken Getz Tufts, 4, 5 – PwC Research

Standards are not just a tool…combined with technology they are the foundation for reinventing the biopharma development process and enabling automation

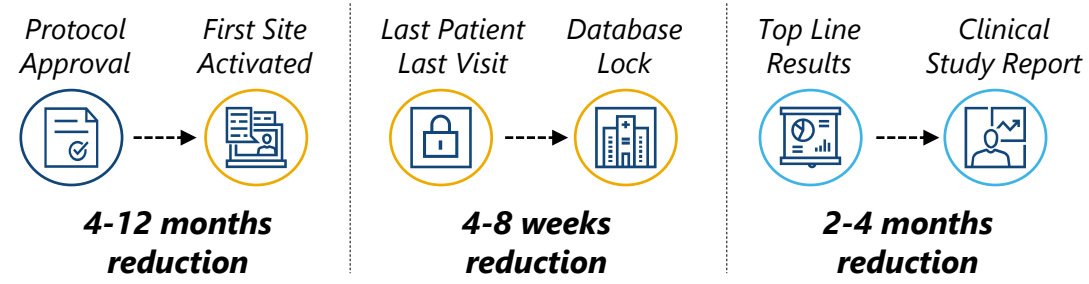
Future-State Trial Lifecycle



AI & Automation Use Cases

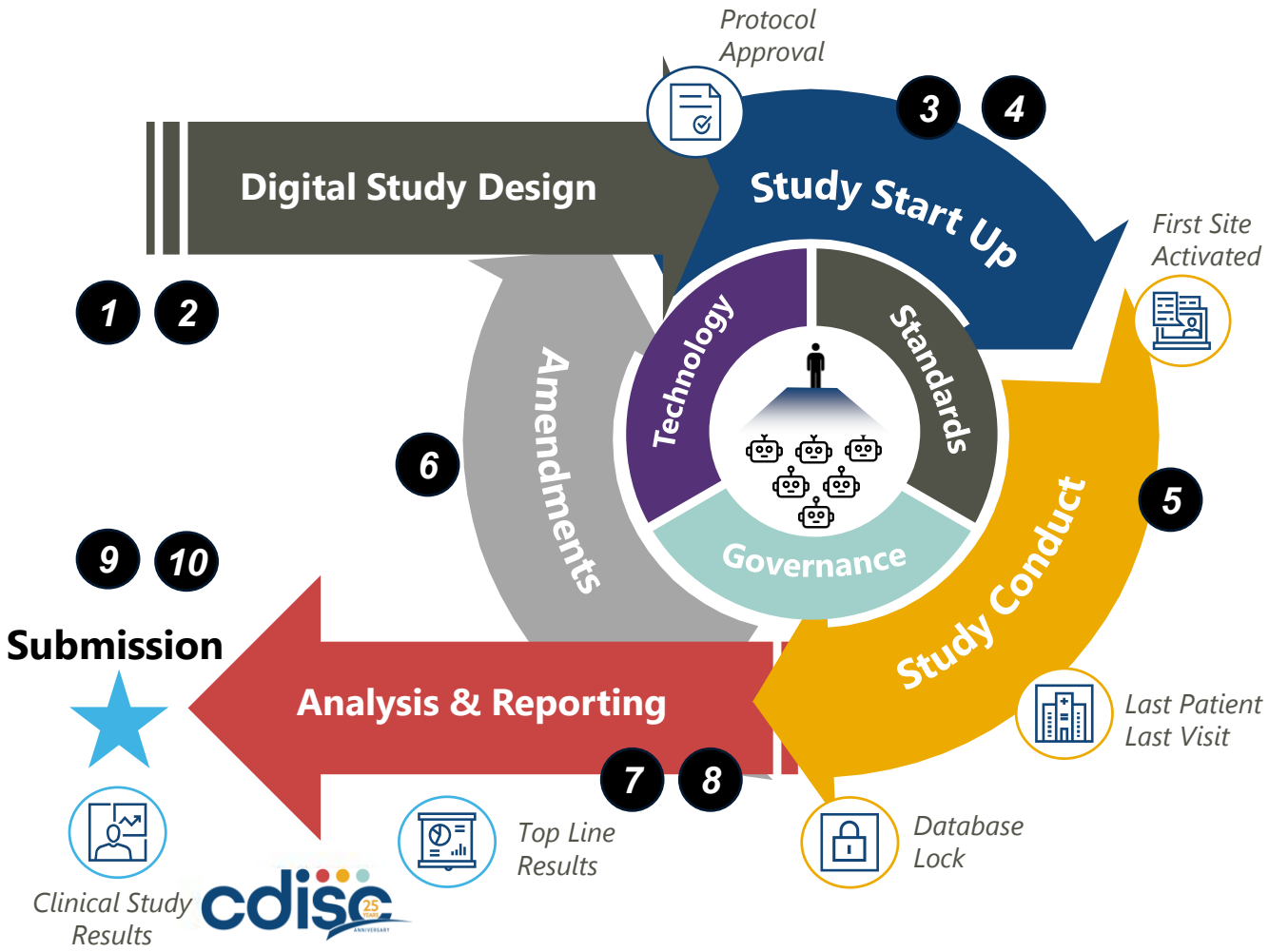
1. Protocol Design Optimization
2. Full Text Protocol Generation
3. Study Artifact Generation
4. Site Budget and Contracting
5. Automated Clinical Data Flow
6. Generation & Implementation of Amendments
7. Automated Generation of Analysis Dataset
8. Automated Generation of TLFs
9. eCTD Population and Automatic Linkage
10. Draft CSR Generation

Anticipated Net Cycle Time Reduction



Select use cases for AI and Automation within Digital Study Design and Study Startup

Future-State Trial Lifecycle

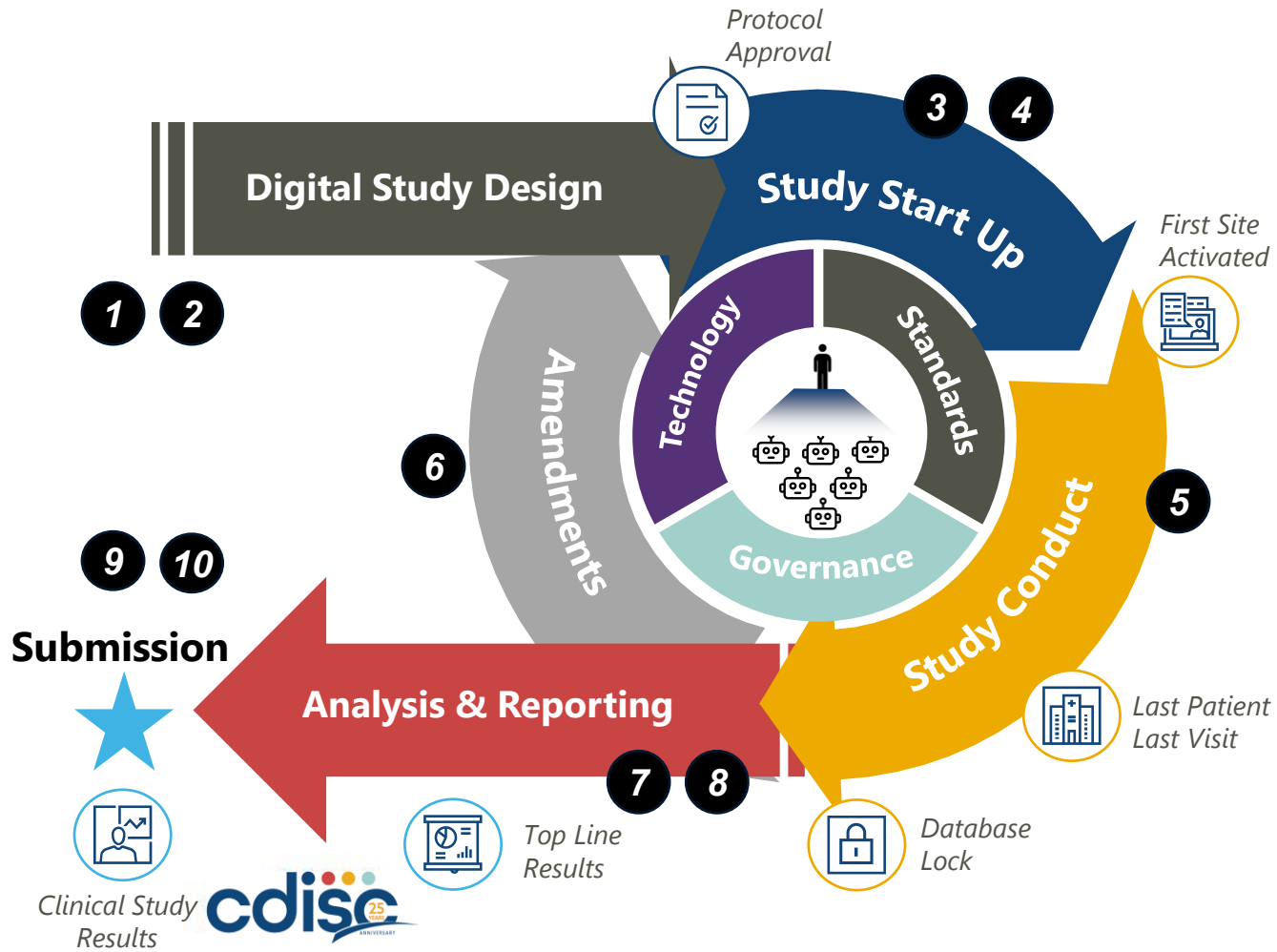


AI & Automation Use Cases

1	**Protocol Design Optimization**	Deployment of a trial design solution to optimize eligibility criteria and schedule of activities for cost, timelines, and feasibility
2	**Full Text Protocol Generation**	Creation of standardized clinical trial protocols from structured data inputs, enhancing efficiency and consistency in trial design and documentation
3	**Study Artifact Generation**	Automated generation of key study documents (e.g., informed consent, site contracts, etc.), automated system builds, and executable data transfers agreements
4	**Site Budget and Contracting**	Development of predictive models on enrollment feasibility, site health/risks and cost
5	**Automated Clinical Data Flow**	Move, standardize, and process data from collection to analysis with minimal intervention and automated conformance and integrity

Select use cases for AI and Automation from Study Conduct through Study Results and/or Submission

Future-State Trial Lifecycle



AI & Automation Use Cases

6	**Generation & Implementation of Amendments**	Automation of new protocol sections based on prompts or historical insights; Impact analysis and automating downstream artifacts
7	**Automated Generation of Analysis Dataset**	Leveraging metadata and standards to automate creation of datasets
8	**Automated Generation of Analyses**	Leveraging metadata and analysis datasets to automate creation of analyses
9	**eCTD Population and Automatic Linkage**	Compilation and pre-population of required modules and automatic linkage of documents and data
10	**Draft CSR Generation**	Leveraging GenAI to convert trial data into structured narrative text

CDISC 360i Elevator Pitch…

CDISC 360i is transforming clinical research by digitizing study design through analysis making metadata interoperable across the entire study lifecycle. With reusable standards and end-to-end automation, 360i eliminates manual tasks, increases data quality, enables AI, ensures traceability and consistency, and empowers the industry to deliver clinical trial results faster, more efficiently, and at a lower cost accelerating the delivery of new therapies to patients

Future standards provide the foundation to reinvent the process and enable automation

Accelerates Clinical Study Start-Up & Reduces Time to Insight

- Automated workflows and eliminating error prone tasks results in moving from **months long setup to streamlined processes** in weeks
- Faster, machine-readable digital study information **improves speed and accuracy**

Drives Quality & Consistency Across the Data Lifecycle

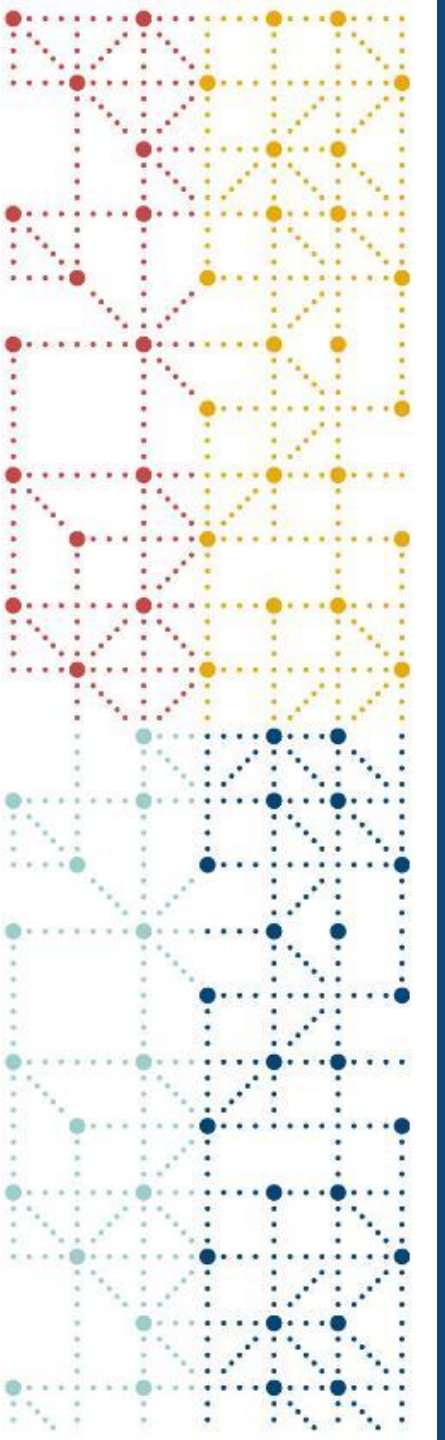
- Standards driven automation **ensures clinical data is consistent, traceable, and reusable**
- Real-time, embedded validation **reduces risk of costly errors and regulatory compliance issues**

Enables Seamless Interoperability & Future-Proofed Data Ecosystem

- Connected study through analysis information in a single framework **empowers industry for greater interoperability**
- Supports growing complexity of trials with **scalable and future-ready data architectures** based on connected standards

Improves Stakeholder Engagement & Regulatory Compliance

- **Industry benefits from faster & smarter study designs**, improved cross-functional alignment, and a streamlined data flow
- Regulatory agencies **receive more consistent, high-quality 'clickable' data submissions**



Thank You!