



Zelta: Enablement Bundle

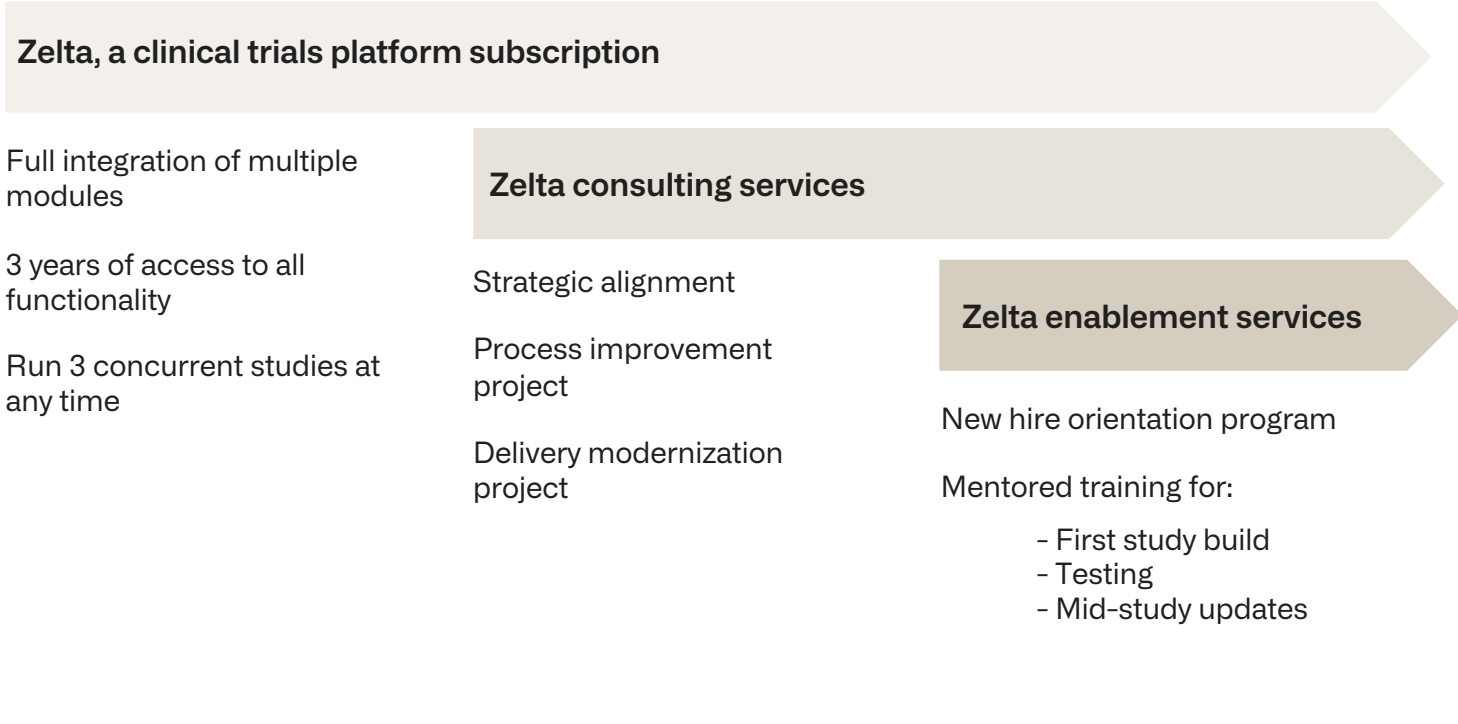


At Merative, our
goal is to make
clinical
development
simpler
for our sponsor
partners

You + merATIVE

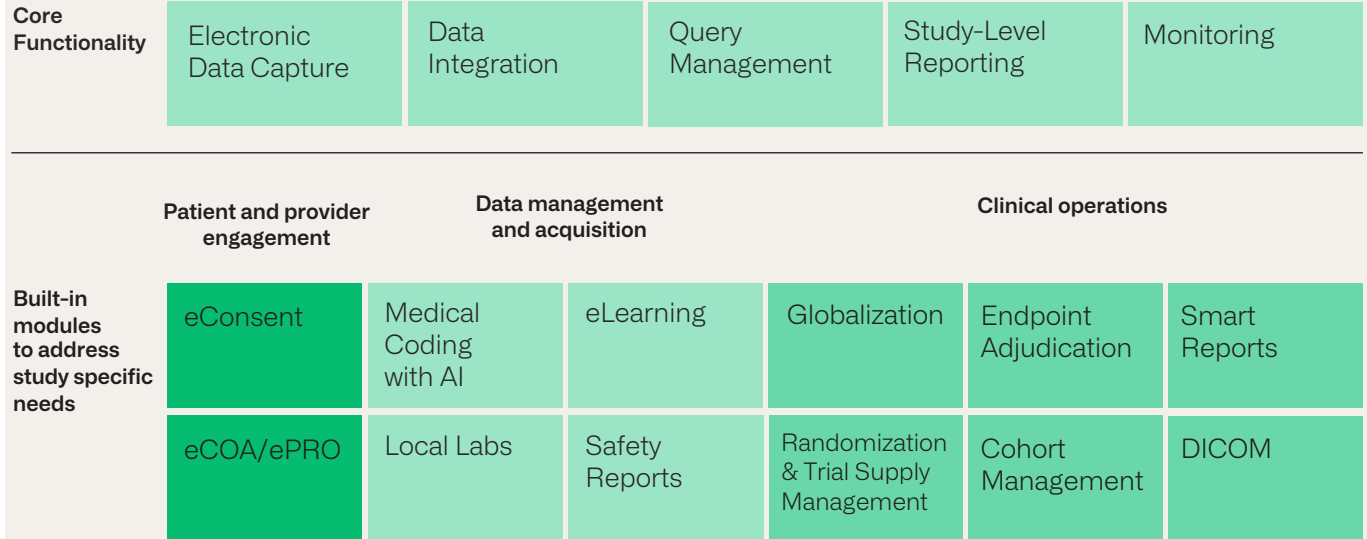
- Reduce overall spend on clinical development
- Modernize your systems and process
- Improve efficiency of your delivery teams

Our platform and services bundle helps improve your study delivery methodology, control your costs and modernize your systems.



One user experience on a single code base across the entire unified Zelta clinical trials platform

- **3.6K+** studies have been executed across **109** countries.
- **1B+** clinical data points collected in Zelta.
- **1.5M+** electronic patient-reported outcomes (ePROs) have been generated through direct patient interactions.



Consulting services

- Prioritize key organizational objectives that will direct all
- Define clear success parameters and expectations from leadership.
- Create formal project charter to govern partnership.

Strategic alignment

Process	Key questions
<ul style="list-style-type: none">- Conduct 3- 5 interviews (30 minutes)- Hold readout and collect feedback (1 hour)- Refine materials and provide summary- Develop project charter based on outputs	<ul style="list-style-type: none">- What is the organizational strategy and what are the major priorities for the next three years?- What role does clinical trial data management play in your organization strategy?- How has data management performed in the past? What are the key problem areas to address?- What objectives should the partnership with Merative focus on, e.g., turnover, cycle time, cost?- How should we measure success?- What lessons can we apply to the rest of the org strategy?

Consulting services

- Perform Input-Process-Output(IPO) and instructional design assessment across process.
- Propose Modernization, Standardization and Improvement (MSI) Plan.
- Implement MSI plan including updates to SOP, work instructions, design and standards library.

Process improvement and modernization

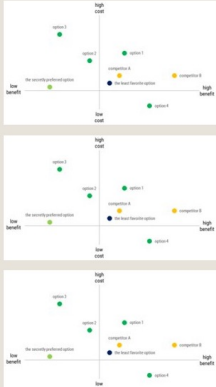
Input-Process-Output Analysis (Example Initial Database Design)

Input	Process	Output
<ul style="list-style-type: none"> • Clinical operations provides trial summary, methodology, initial stats schema (stats), geo/pop, initial form design, visit schedule • Medical affairs provides safety and compliance guidelines • Data manager, Clinical Ops, IT, ECT leadership approval with project expectations 	<ul style="list-style-type: none"> • Develop initial forms (pull from library or CDSIC) • Develop visit schedule • Simple queries • Develop complex page dynamics • Develop complex queries • • Informal review of database with Clinical PM (working session) • Formal UAT 	<ul style="list-style-type: none"> • Formal study design documents signed for approval • Go live signatures confirmed • Database live

Modernization, Standardization, Improvement Plan

Modernization	<p>QA- X hours, \$Y (recurring, one-time),</p> <ul style="list-style-type: none"> • Testing practices update for SOP- included in contract, will cover during X phase. • Testing practices for DM team included in contract, will cover during X phase • Tooling to generate test cases • Tooling to capture OE • Fundamental update to people
Standardization	<p>Database design</p> <ul style="list-style-type: none"> • Train on CDSIC. \$2,700 per person, train DM \$5,400 • Develop a standard CDSIC library for clinical ops and DM to use. 160 hours, 50 external
Improvement	<p>New Hire Orientation (turnover, cost per HC, more efficient onboarding), Study Testing (cycle time, error reduction)</p> <ul style="list-style-type: none"> • Add a level of maturation to WH (visuals, more operational definition, expectations) • Update New Hire Orientation program • Create NEW SOP for study testing

Cost Benefit



New hire orientation

Program template to on-board and educate resources involved in the study design process

E-binder delivered in digital format that provides standardized and efficient instructions



New hire orientation (NHO) program

- Using output from the process design, set up standardized expectations for delivery
- Provide a program for new hires on database design, including:
 - Process maps
 - Work instructions
 - Roles, responsibilities and expectations
- Governance elements to broaden shared knowledge and reduce on-boarding costs

Objectives

- To have a structured and standardized NHO that is timely and efficient
- To decrease turnover through providing training to new hires that enables competency and satisfaction in their role
- To have an easily accessible and usable resource for new hires to utilize
- To decrease the cost of training new hires through a program that is efficient and cost effective
- To clearly outline roles, responsibilities, expectations and instructions for new hires

Enablement services – Mentored training

Build

- Build your first study in collaboration with our expert trainers.
- Complete a go-live ready study design with step-by-step guidance on how your specs work in the platform.

Test and validate

- Leverage our trainers for best practice suggestions.
- Test your output with our trainers or with automated testing.

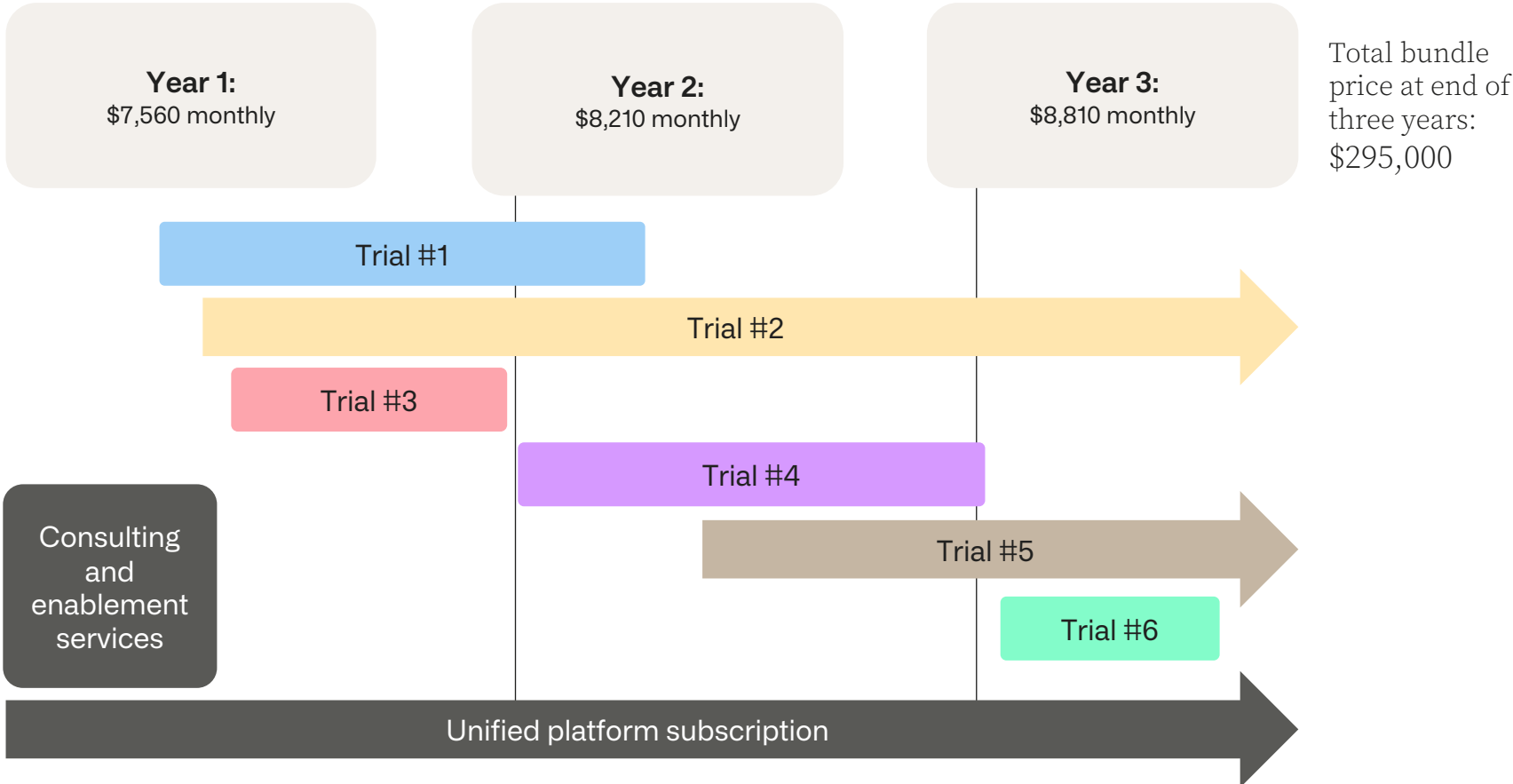
Mid-study update (MSU)

- Work with mentors on your first mid-study update deployment.
- Develop documentation to enable best MSU practices.

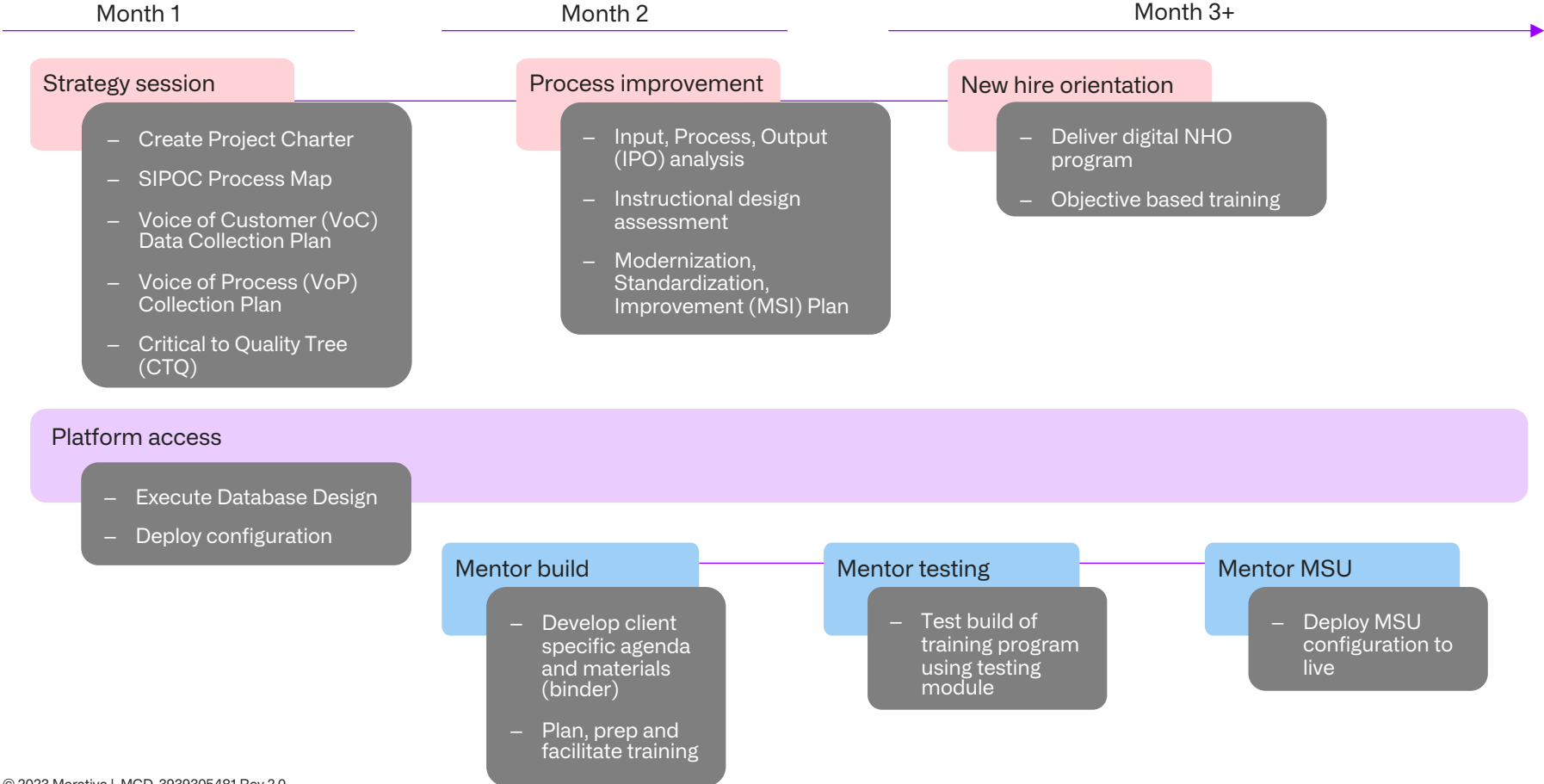
Sample training agenda

Session 1	Session 2	Session 3
<p><i>Introduction</i></p> <p>Study Startup</p> <ul style="list-style-type: none">• Adding studies• Study Attributes• Study Tags• Import Full Study• Study Permissions <p>Study Process</p> <ul style="list-style-type: none">• Import Study Process• Design Attributes (Required)• Design Attributes (Optional)• Icons• Roles• Subject Status• Page Status• Query Types	<p>Study Build</p> <ul style="list-style-type: none">• Import Pages• Revisions• Code Lists• Pages (Simple Queries / Simple Dynamics / Permissions)• Visits• Visit Schedule Order / Grid• Visit Permissions• Visit Rules• Cross Page / Complex Queries and Dynamics / Au calculations• Study Reports	<p>Study Deployment</p> <ul style="list-style-type: none">• Publish Icons• Flush Study• Go Live• Site and User Management• Study Messages• Recurring Jobs Summary• Import Sites <p>Study Closeout</p> <ul style="list-style-type: none">• Exports and Documentation• Lock/Close <p>Miscellaneous</p> <ul style="list-style-type: none">• Spell Check• How to get Designer Certified

Sample delivery experience over three years



Sample service delivery timeline – First three months





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