medidata

THE
ARCHITECTURE
OF
HOPE™

Medidata Implementation Services

February 2018

About Us

1K
customers

100+
industry partners

18 of top 25
pharma customers

18 of top 25
med device customers

The Medidata Ecosystem

2K+

employees

100K+

certified data managers & clin ops professionals

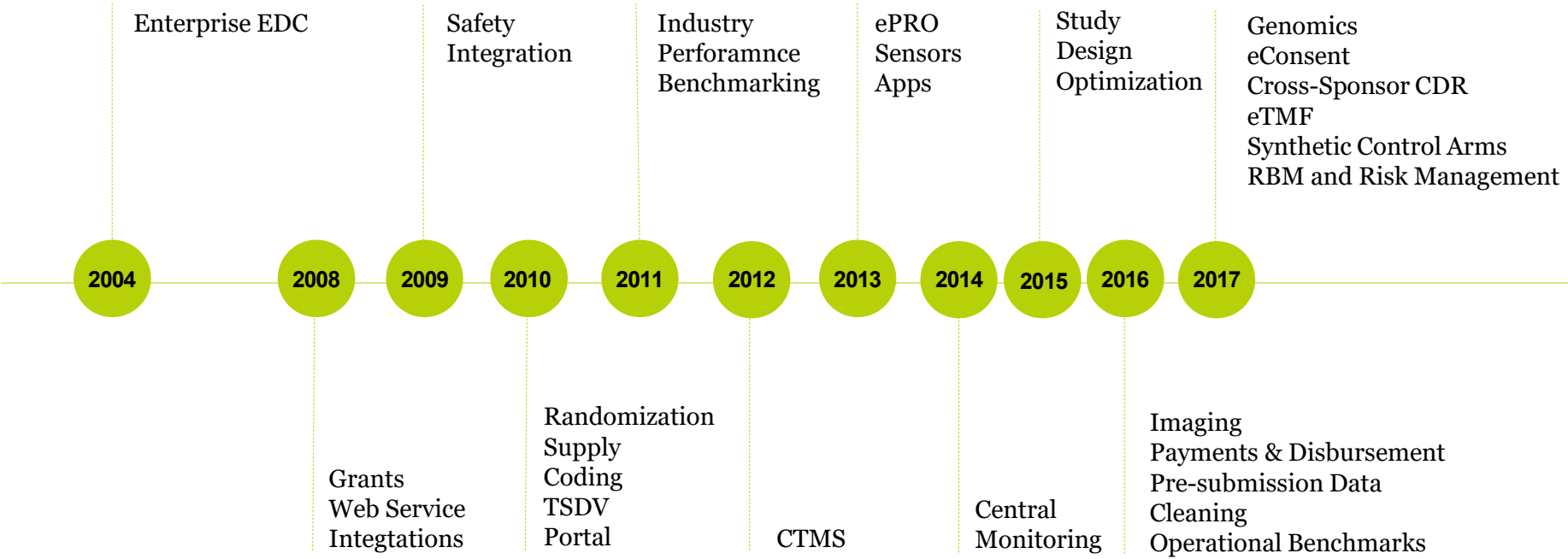
500K+

site/sponsor relationships

1M+

completed eLearning courses

Our innovation…



We are the #1 Ranked Professional Services Group in Clinical Development.

Our professional services have you covered.

#1

ranked in clinical development services*

14K

studies under our belt

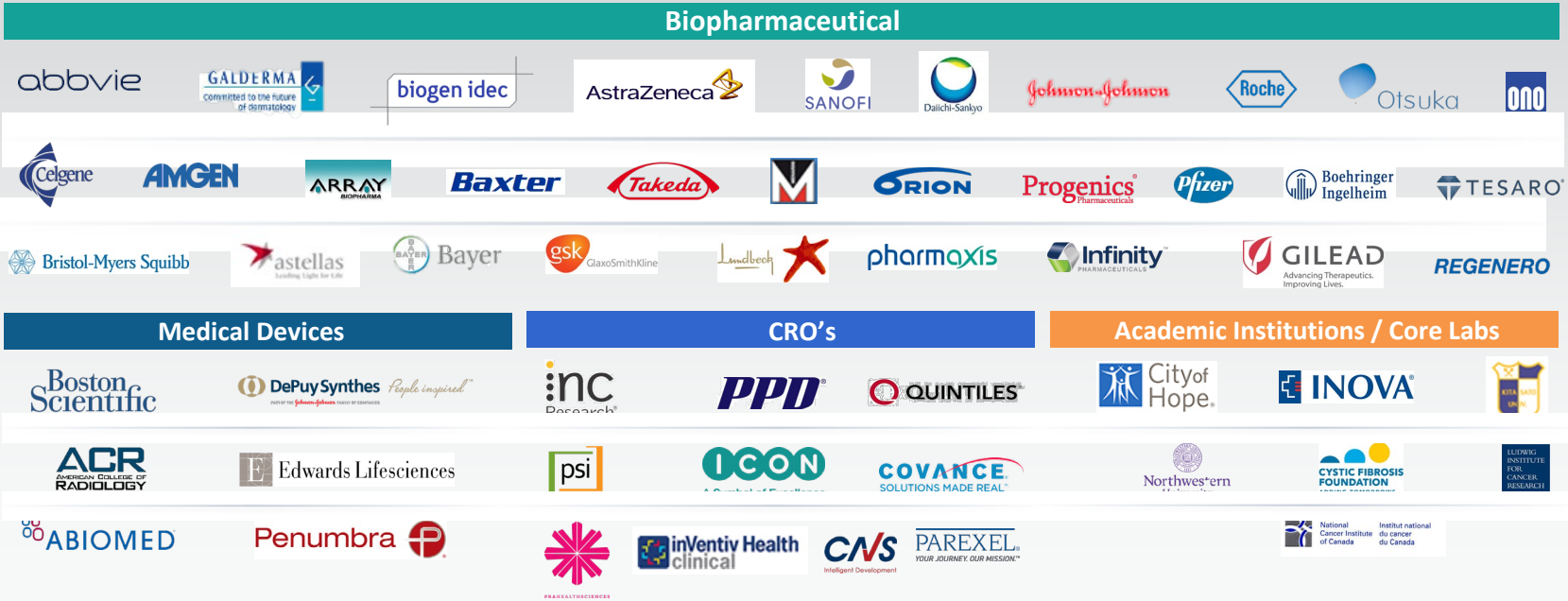
8

weeks or less to implement our solutions

**Survey of Life Science end-users and decision makers in July 2017. N=120. Survey conducted by Life Science Strategy Group in partnership with Medidata Market/Competitive Intelligence*

Proudly Serving Innovative Life Sciences Organizations

- Pharmaceuticals
- Consumer Health
- Medical Technology and Devices
- Generics
- Health Start-ups
- Biotechnology / Biosimilars
- Global Health Authorities
- Wholesalers / Distributers
- Service Providers



The most complete platform in the industry and unified by the largest clinical data repository.

Rave
Medidata Clinical Cloud

End-to-End Solutions for Clinical Trials

Scientific Insights

- Omics with Biomarker Discovery
- Synthetic Control Arm™
- Synthetic Control Database™

Study Planning

- Site Grants

Study Startup

- CTMS
- RBM
- eTMF
- Site Payments
- RCM
- TSDV
- Site Monitoring
- RACT
- Study Management

Study Conduct

- Rave EDC
- Coder
- Imaging
- Wearable Sensors
- Safety Gateway
- eCOA
- RTSM
- CSA
- eConsent
- Virtual Trials

Study Closeout

- Trial Assurance

Medidata Enterprise Data Store (MEDS)

Security is our #1 priority.

People

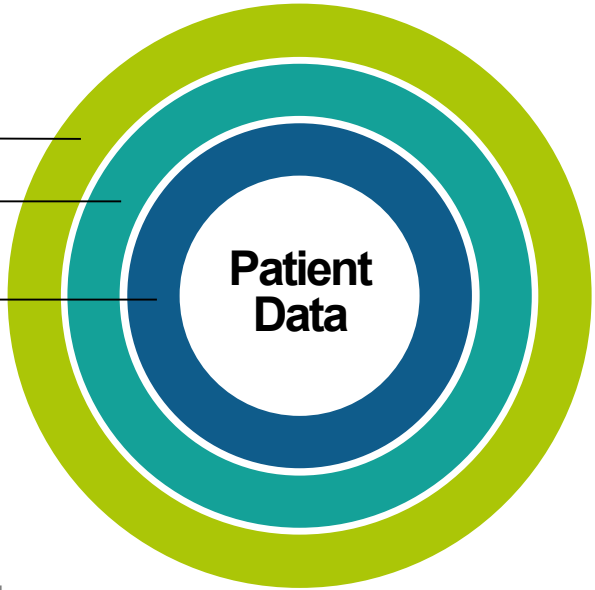
- Security and Compliance
- Expertise and Experience
- Government regulation security certifications
- Real-time security management 24X7

Process

- End-to-end security and privacy
- Validated controls in place for application, IT and network systems
- Advanced detection and response capabilities

Technology

- Single point of access for all data types from any data source
- Clinical Cloud Computing with high availability and security
- Gain Actionable Insights Across a Unified Platform



Medidata's Clinical Cloud Platform

Benefits our Customers have seen in Partnering with Medidata

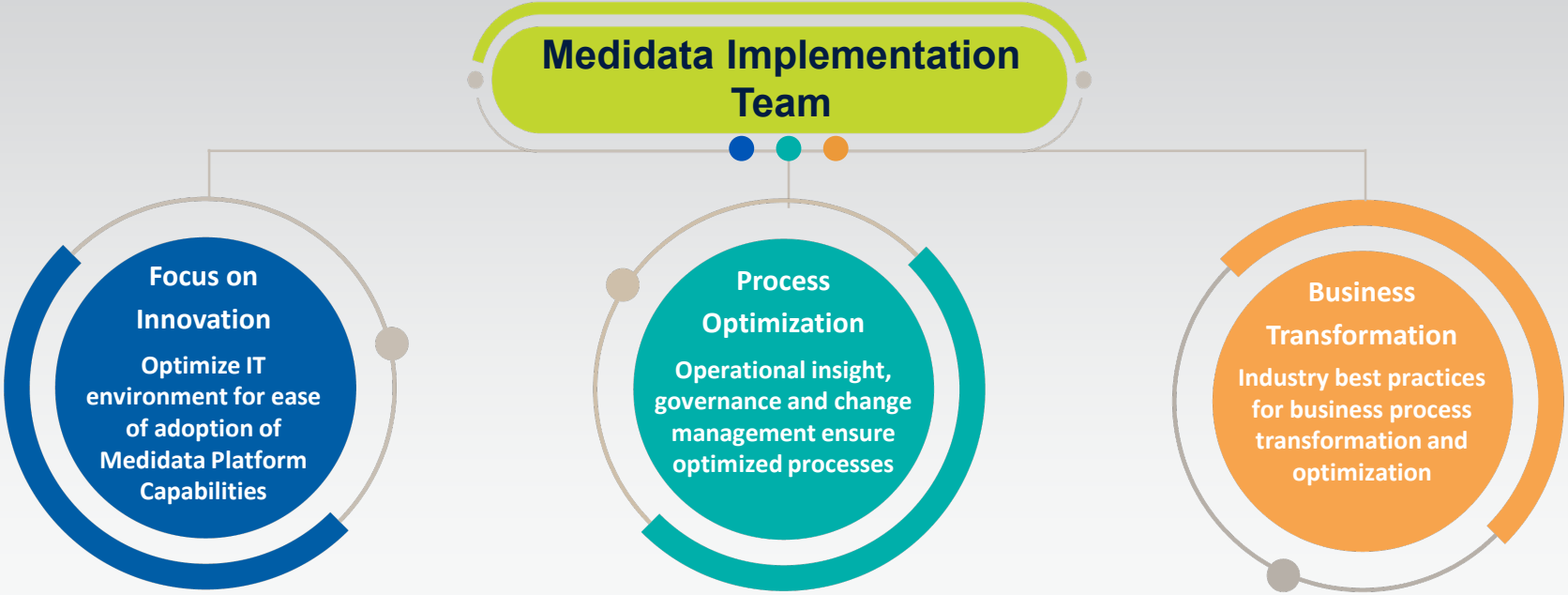
Objective	Expected Results	Time	Cost	Quality
Increase Speed to Patient via CDMS	• Faster study builds and database locks • Reduction in data review, query, and serious adverse events (SAE) processing	↓	↓	↑
Richer Analysis and Sharing of Clinical Data	• Continuous improvement driven by analytics	↓	↓	↑
Enable Complex and Innovative Studies	• Single platform for all study types • Faster and more comprehensive decision making	↓	↓	↑
Agility to Process Unique Patient Data Types	• Agile clinical development platform • Future-proofed against changes in disease area focus	↓	↓	→
Optimize Flexibility and Total Study Cost	• Decrease data management costs by 25-45%	↓	↓	→
Reduce Operational, Compliance, and Technology Risks	• Reduced risk based on Medidata technology • Reduce risk based on R&D Services	↓	↓	↑
Positioned to Meet Global Regulatory Requirements	• Highest level of global compliance today • Medidata influence on the future of global regulations	→	→	↑

Medidata Implementation Team (MIT)

89+ Professional Services & Consultants

19% **>10 YRS** of Service

25% **5-10 YRS** of Service



The MIT Advantage

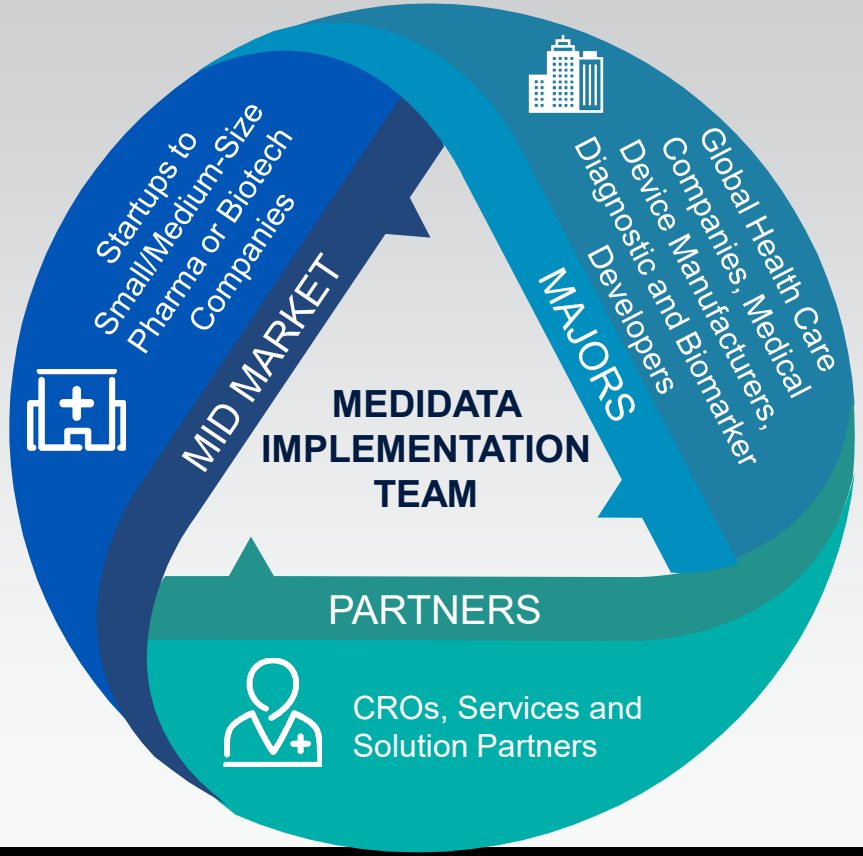
Maximize the value of Medidata products by providing unmatched expertise in clinical trial processes and technology

Support entire MDSOL Solutions through unmatched expertise in clinical trial process and technology

Provide consultation as your "trusted advisor"

Provide post "go-live" support

Medidata Implementation Team



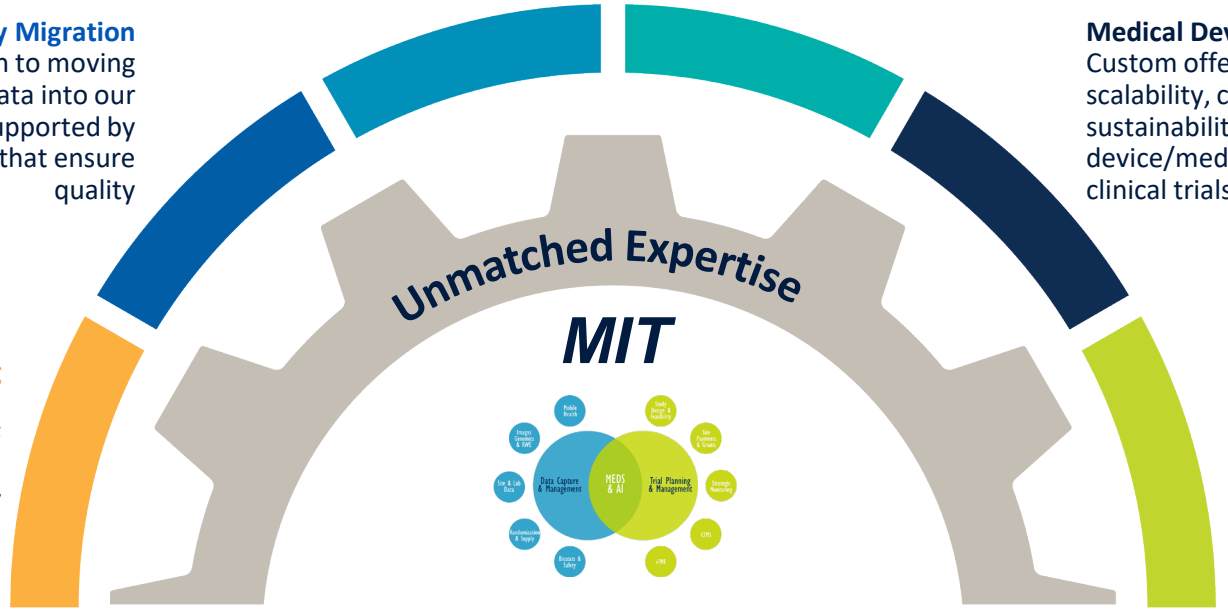
MIT Support's Entire Medidata Platform

Operational Support Model
Program Management
Governance

Rave Offering
Ongoing support for your trial supply and randomization

Study Migration
Tool based approach to moving existing clinical data into our platform that is supported by optimized processes that ensure quality

Medical Device Offering
Custom offering with the scalability, configurability, and sustainability required by device/medical device clinical trials



Phase One Offering
Configuration of Phase I studies leveraging eCRF forms and edit checks from a pre-configured library

Advanced Technical Services
Portal Integration Image Viewer Integration ODM Integration Custom Reports

End to End Implementation Across Medidata Platform

Medidata Implementation Team

Ensures customers maximize technology value through unmatched expertise

Medidata Implementation Team

- Unmatched Expertise
- Collaborative Project Management
- Operational Excellence

Medidata Expertise Provides…

Implementation

Proven methodology and consultative approach delivers fast, flexible and optimal trial design

Imaging

Proven imaging methodology insures seamless integration with EDC and 3rd party viewing tools while supporting Endpoint Adjudication Committees (EAC)/ Clinical Endpoint Committees (CEC)

Technical Services

Accelerates your study through integration at the application, analytic and data levels

Delivery Optimization

Reduces issues found in UAT ensuring the integrity and reliability of clinical data through collaboration best practices between project designer and client tester

Efficient Trials through…

- **Lower Costs and Reduced Risk**
- **Complete Support of Medidata Platform**
- **Optimized Implementation**
- **Fully Optimized Processes**

Medidata Implementation Team Success

Proven Customer Results

95%
Customer Satisfaction

100%
Customer Retention

1,000+
Studies built to Date

Better Than Industry Median eCRF Study Design Cycle Times

Study	eCRF Design Period (Weeks)
PR-10-5014-C	3.3
4010-01-001 Part 2	4.4
PR-11-5012-C	5.6
OPEN LABEL QTC-PR-30-5011-C	6.9
PR-11-5022-C	7
PR-10-5013-C	7.1
QUADRA_PR-30-5020-C	10.9
4010-01-001	11.9
PR-11-5016-C	12.7
4020-01-001	13.4
PR-30-5015-C	15.1
PR-30-5017-C	16.7
BRAVO PR-30-5010-C	20

Average eCRF design period cycle time = 10 weeks; industry median = 14 weeks

Directional Value Attainment Per Study Designed (Compared to industry median)		Notes
eCRF design period (in weeks) – Industry Median	14	From Medidata Insights
eCRF design period (in weeks) – Tesaro	10	From Medidata Insights
Tesaro's study design is faster than Industry Median by (in weeks)	4	Calculated (=14 weeks - 10 weeks)
Number of FTEs designing studies	2	Estimate validated by Tesaro team
Number of hours saved (40 hours per work week)	320	Calculated (=4 weeks * 2 FTEs * 40 hours per week)
Data Manager cost per hour to design eCRF	$135	Medidata PICAS benchmark
Total study design cost savings per study	**$43,200**	**Calculated (=$135 per hour * 800 hours)**
Total study design cost savings across all 17 studies	**$561,600**	**Calculated ($43,000 savings per study * 13 studies)**

* Data for studies 3000-PN162-01-001, PR-20-5006-C, PR-11-5021-C may not represent actual eCRF design periods since the builds were started and then put on hold; to avoid skewing the results these three studies were not included in the analysis.

MIT Case Study: Driving Operational Excellence

Reductions in eCRF Design Period from Implementing Global Library

64% Reduction	47% Reduction	46% Reduction
Customer 1 reduced Phase II and III study design periods from 19 weeks to 6.7 weeks Current Global Library reuse = 28%	Customer 2 reduced Phase II and IV study design periods from 18.9 weeks to 10 weeks Current Global Library reuse = 78%	Customer 3 reduced Phase I, II and III study design periods from 11.0 weeks to 6 weeks Current Global Library reuse = 71%

Data illustrated in the proof points above are current as of March 2016. Data Source: Medidata insights Trend Analysis for eCRF Design Period and, eCRF reuse and eCRF reuse from Global Library.

Key Value Drivers

- Customer #1, #2, and #3 proactively managed the eCRF design process and maximized the value of standards
- Leveraged the Global Library to facilitate the process of reusing study components
- Drove efficiency in study startup resulting in reduced duration to “go-live” through improved study startup efficiencies
- Their Global Library contained validated DEC elements (forms, edit checks, etc..) resulting in reducing the need for additional testing (which further reduced the cost of the validation process)

MIT Medidata Solutions Enable your Process

Scientific Insights

- Omics with Biomarker Discovery
- Synthetic Control Arm™
- Synthetic Control Database™

Study Planning

- Site Grants

Study Startup

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- eTMF
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Medidata Enterprise Data Store (MEDS)

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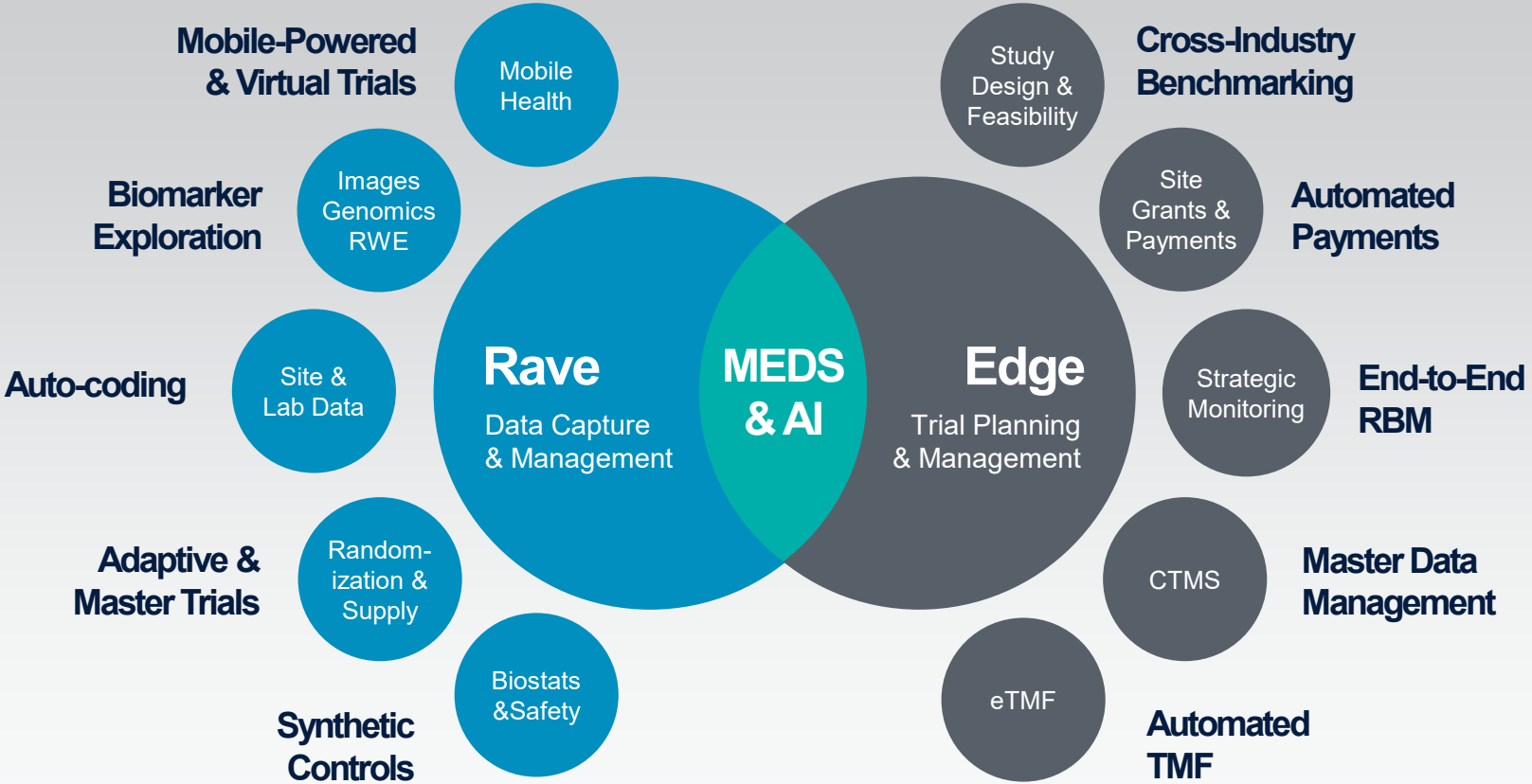
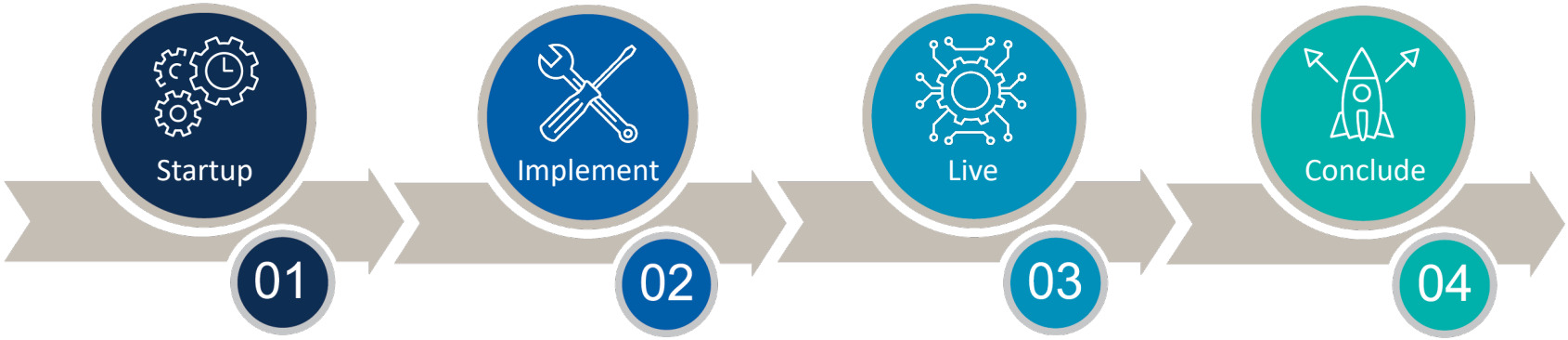


MIT Solution Implementation Life-Cycle (SILC)

Full project life-cycle support



- Joint development of SO based on requirements
- Project development meeting, setup, and protocol review

- Develop, test and deploy all components

- Full project life-cycle On-going Support for business users/roles involved
- Change Management

- Provide End-of-Project deliverables identified in Project development meeting; Database lock

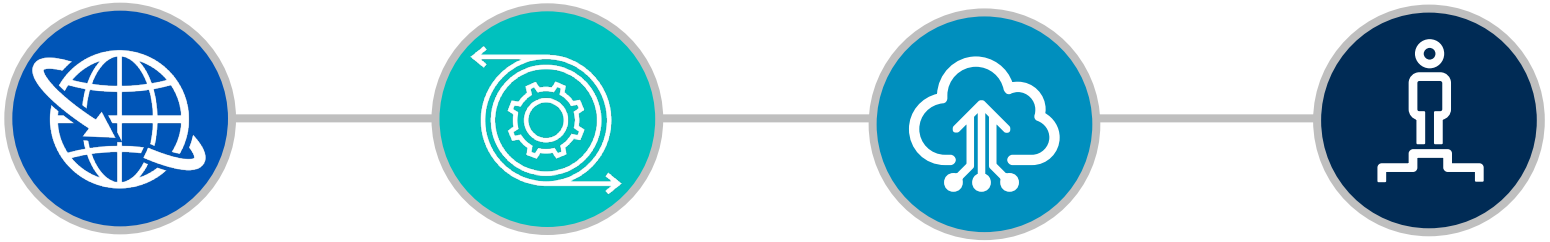
MIT Processes are Enablers of Success

Reduce risk through collaborative project management
leveraging standardized best practices with technologies: ie. Smartsheet, C-dash Organization, Zendesk, Google Suite, and SILC

Save time with a proven, evolving and innovative methodology
for rapid configuration of Medidata platform

Unmatched enterprise and experience
accelerating your clinical trial while ensuring high quality

MIT Setting New Standards for Image Management



GLOBAL EXPERIENCE

- 100+ Countries
- 5,500+ Global Sites
- Broad expertise in a variety of therapeutic areas

POWERFUL API's

- EDC integration
- Experience with 3rd party viewing tools

CONFIGURABLE WORKFLOW MANAGEMENT

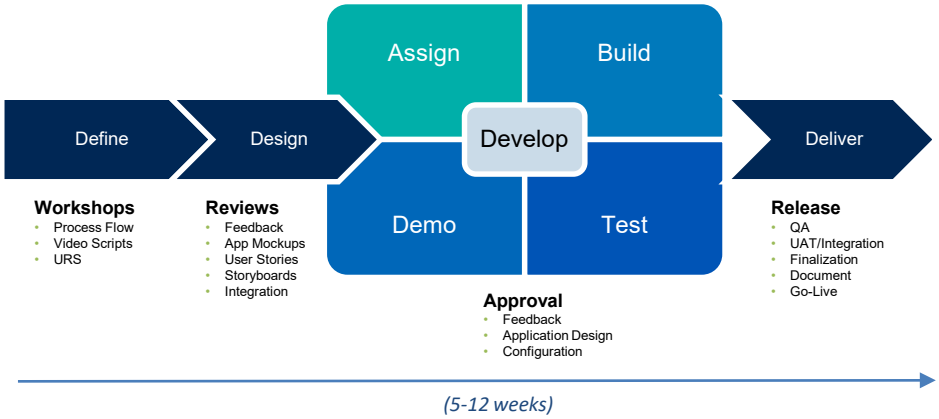
- Support in Event Adjudication (EAC)
- Support in Clinical Events Committee (CEC)

IMAGING ACCREDITATION PROGRAM

- Instructor-led courses incorporate real-world examples
- Hands-on experience tailored to roles

MIT eConsent Customer Realized Value

Configuration



Realized Value

- 75% Memory recall with Enroll®
- 58% Memory recall with Paper
- Patient Centric Design
- Improve Patient Site Relationship
- Qualified Patients
- Reduce patient drop outs
- Reduce monitoring costs
- Automated reporting
- Real-time visibility of enrollment data
- Remote consent patients
- Reduce audit and inspection findings
- Manage consent versions and amendments
- Zero loss paperwork
- Reduce cost with Integrated Platform

MIT eTMF Ensuring Seamless Management of your Regulated Content

- Quality with Edge
  Quality with SOP
  Implementation
- Document Migrations
  / Archive
  Implementation
- Document Migration
  Consulting
- Edge Upgrade
  Support
- Administration
  Support
- Quality with SOP
  Consulting
- eTMF Consulting
- eTMF Management
  and Implementation

Integrated platform
for managing both regulated and nonregulated content

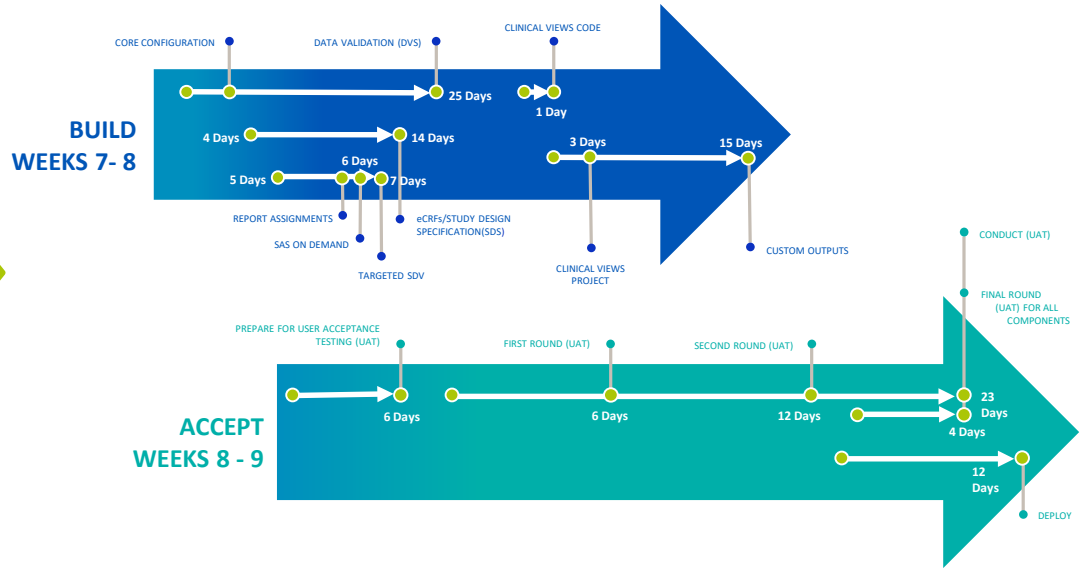
Incredibly intuitive
even for the occasional user. Mobile accessible. Users can quickly find the content they need, when they need it.

Rapid deployment
with minimal resources, supported by pre-built, pre-validated functionality and validated content migration

Cost-effective
by leveraging scalable cloud technology

MIT Typical Implementation Timeline

IMPLEMENT	50d	09/22/17	11/30/17
Build	36d	09/22/17	11/10/17
Core Configuration	4d	09/22/17	09/27/17
eCRFs/ Study Design Specification (SDS)	14d	10/03/17	10/20/17
Data Validations (DVS)	25d	09/22/17	10/26/17
Clinical Views Code Settings	1d	10/30/17	10/30/17
Clinical Views Project Settings	3d	10/23/17	10/25/17
Custom Outputs	15d	10/23/17	11/10/17
Targeted SDV	7d	10/10/17	10/18/17
SAS on Demand	6d	10/10/17	10/17/17
Report Assignments	5d	10/10/17	10/16/17
Accept	42d	10/04/17	11/30/17
Prepare for User Acceptance Testing (UAT)	6d	10/04/17	10/11/17
Conduct UAT	23d	10/26/17	11/27/17
First Round UAT	12d	10/26/17	11/10/17
2nd Round UAT	12d	11/06/17	11/21/17
Final Round UAT for all components	4d	11/22/17	11/27/17
Deploy	12d	11/15/17	11/30/17



Strengths of Medidata Implementation Team

Unmatched Expertise Ensuring Optimized Trial Outcomes

All Medidata Solutions

- Experienced in implementing Medidata's latest solution versions
- Multi-product deployments
- Single contract – no 3rd party contracts (Imaging, eCOA)

Study Build Time

- Faster build times
- Attaining target FPI dates
- Faster subsequent studies

Quality of Build

- Access to latest training and industry best practices
- Continuous process improvements

Flexible Resource Pool

- Global distribution of resources

Focus on Core Competencies

- Customer's build hope
- Medidata accelerates it

Professional Services Helps Ambit Biosciences Successfully Rescue Three Critical Oncology Studies

The Challenge

- Ambit needed to transition three critical oncology studies in progress
- Limited to a tight six month period to for complete transfer of knowledge, documentation and data
- Resources strained with volume of study data and time needed for migration

The Solution

- Medidata Professional Services reconfigured roles and workflows for each of the three studies to better fit Ambit's needs and available resources
- Medidata Project Manager provided recommendations for timelines and transitions based on their experience
- Restructuring of Rave databases – including identifying missing elements from original setup
- Data loaded through Rave Web Services & Synonym tables though Rave Coder

The Results

- Successful study setup with tight timeline constraints and no data loss
- Tailored solution for Ambit's needs based on Professional Service experience
- Transparency during data transfer process and seamless process and reassurance for sites

ambit

"The Medidata Professional Services team led us through the transition process step by step and provided us options along the way. They made recommendations based on our specific needs and style of working."

Mar Reyes
Director of Data Management
Ambit Biosciences

Onconova finds success with a flexible study build model using Medidata Rave

The Challenge

- Manual efforts around patient screening
- Non-documented communication to sites finding eligible candidates
- Variable internal resource availability for study build process

The Solution

- Flexible study build models depended on resource availability and URL ownership including
  - Outsourcing the database build
  - Working with Medidata Implementation services to build studies
  - Knowledge Transferred enabled to configure their own enablement

The Results

- Versatility to outsource data management but maintain data collection in central location
- Custom functionality built with shared experience from Medidata's Professional Services team including notifications and an audit trail of the eligibility discussion
- Reduced costs contracting third party builders
- Eliminated redundancies and efforts starting new projects leveraging a standardized study build operation

ONCONOVA THERAPEUTICS

"We didn't go shopping, we knew we wanted to use Medidata and it was a matter of working to find the right model to fit our business needs."

Patrick Zbyszewski,
Director of Clinical Data Management,
Onconova Therapeutics

Tesaro pushes Medidata Rave to New Capabilities

The Challenge

- Tesaro looked to Medidata's Rave offering to find a solution to help manage clinical trial supplies for an adaptive trial
- Tesaro need a flexible system to adjust dosing and cohort sizes within specific patient populations

The Solution

- Co-development of new functionality within Medidata Rave to enable users to pool clinical supply inventory across multiple trials at the same research site

The Results

- 40% Reduction in packing waste
- 34% Reduction in shipping costs
- 35% Reduction in data entry time
- Flexibility and agility to the clinical supply chain

TESARO™

"The partnership with Medidata resulted in a drug supply management system that included the functionality and priorities we needed, which resulted in a pooling of investigational product at the depot and investigator site levels to maximize the efficient use of the drug "

Simona Cipra
VP of clinical operations from Tesaro

Thank you.

Backup.

Unified Platform

Unified Platform

35%

increase in high-complexity studies

$26B

average cost per drug

Up to 25

discrete systems

Unrivaled expertise

Unrivaled Expertise

46

Novel drug approvals, doubled YoY

>200

innovative, outcomes-based contracts executed world-wide

4x

two-year increase in chief digital officers in pharma

Pioneering analytics

Pioneering Analytics

69%

increase of precision medicines in the next 5

4x

use of medical sensors

3x

increase in likelihood of trial success when including biomarkers

We power operational and scientific innovation with MEDS, the largest dataset in the industry.

Customers Rank Medidata Professional Services #1 in Recent Life Sciences Strategy Group Survey

LIFE SCIENCE STRATEGY GROUP

	Time to complete project	Quality of Implementation	Accessibility of PS Expertise post-implement	Average Score
MEDIDATA	**3%**	**3%**	**3%**	**3%**
ORACLE	(1%)	1%	1%	1%
PAREXEL	(2%)	(3%)	(3%)	(2%)
BIOCLINICA	(0%)	(2%)	(1%)	(1%)
VEEVA	1%	1%	(2%)	(0%)
IQVIA	(1%)	1%	1%	(0%)
COVANCE	(0%)	(2%)	1%	(0%)

PS w/ Percent Above/Below Average

Medidata Transformational Services Leading the Way:

- ***Accessibility*** to Unrivaled ***Expertise***
- ***Quality*** of ***Implementation***
- ***Time*** of Project ***Completion***

- Survey of Life Science end-users and decision makers in July 2017. N=120. Survey conducted by Life Science Strategy Group in partnership with Medidata Market/Competitive Intelligence

Customers Rank Medidata Professional Services #1 in Recent Life Sciences Strategy Group Survey

Medidata Professional Services Customers Rank us #1* in:

Accessibility to unrivaled ***Expertise***

Quality of ***Implementation***

Time of project ***Completion***

Transforming Medidata Customers into Market Leaders:

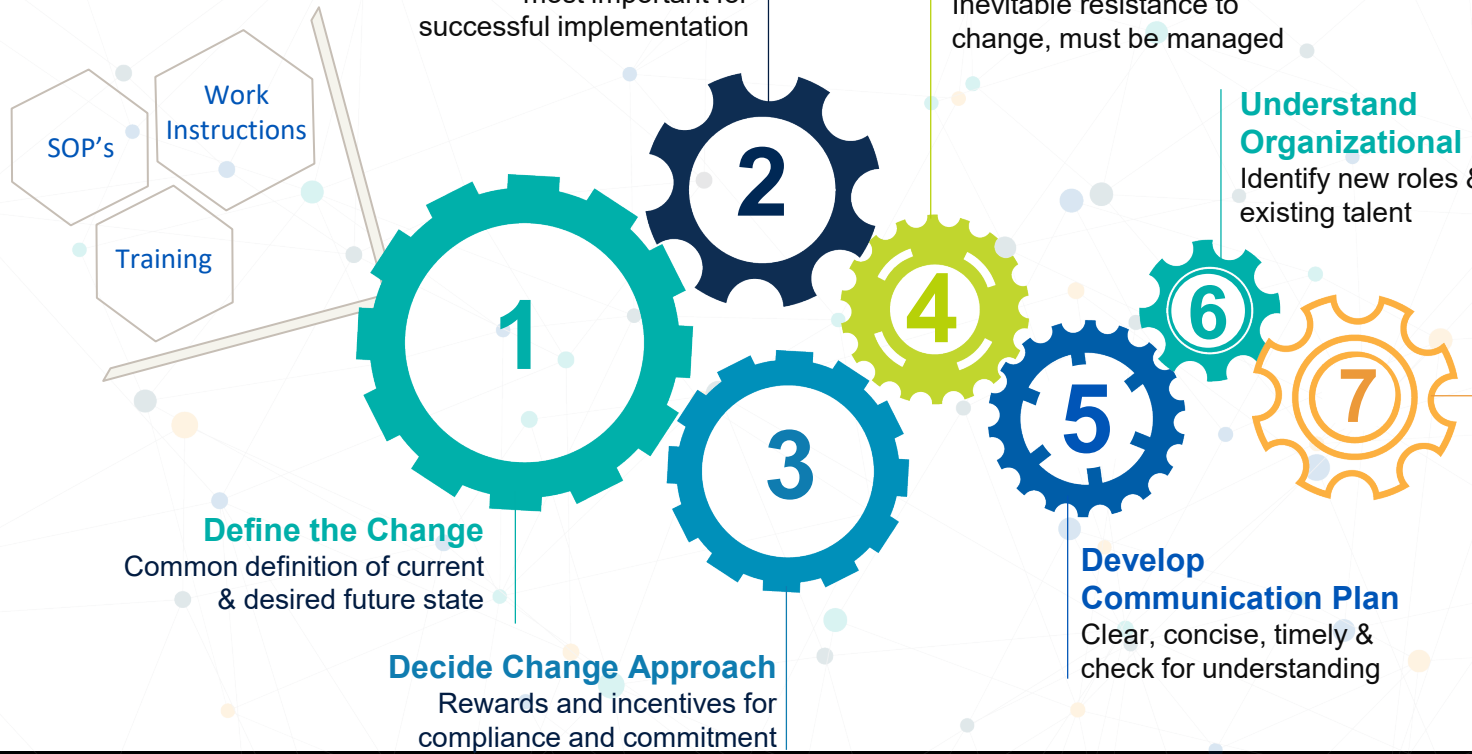
Transforming customers business to get products to patients ***Faster***

Reduced risk, ***Improved*** performance and ***Cost-Saving*** optimized processes

Increased Profitability and ***Faster Response*** to market challenges

*Survey of Life Science end-users and decision makers in July 2017. N=120. Survey conducted by Life Science Strategy Group in partnership with Medidata Market/Competitive Intelligence

MIT Provides a Flexible and Adaptive Change Management



Create Sponsorship
Committed sponsorship = most important for successful implementation

Anticipate Resistance
Inevitable resistance to change, must be managed

Understand Organizational Readiness
Identify new roles & leverage existing talent

Measure Adoption & Performance
Continuous evaluation of change & actions → remediate issues

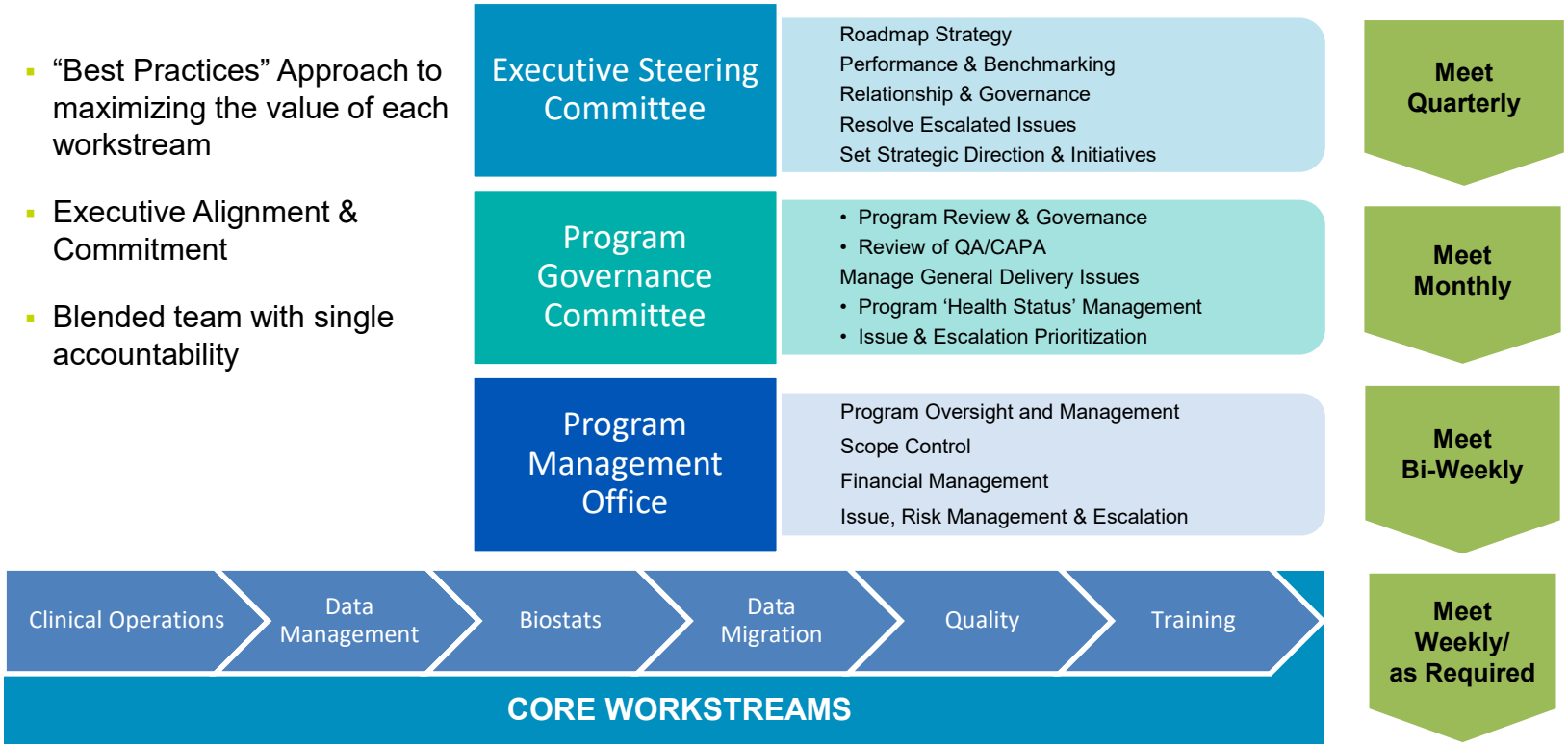
Define the Change
Common definition of current & desired future state

Develop Communication Plan
Clear, concise, timely & check for understanding

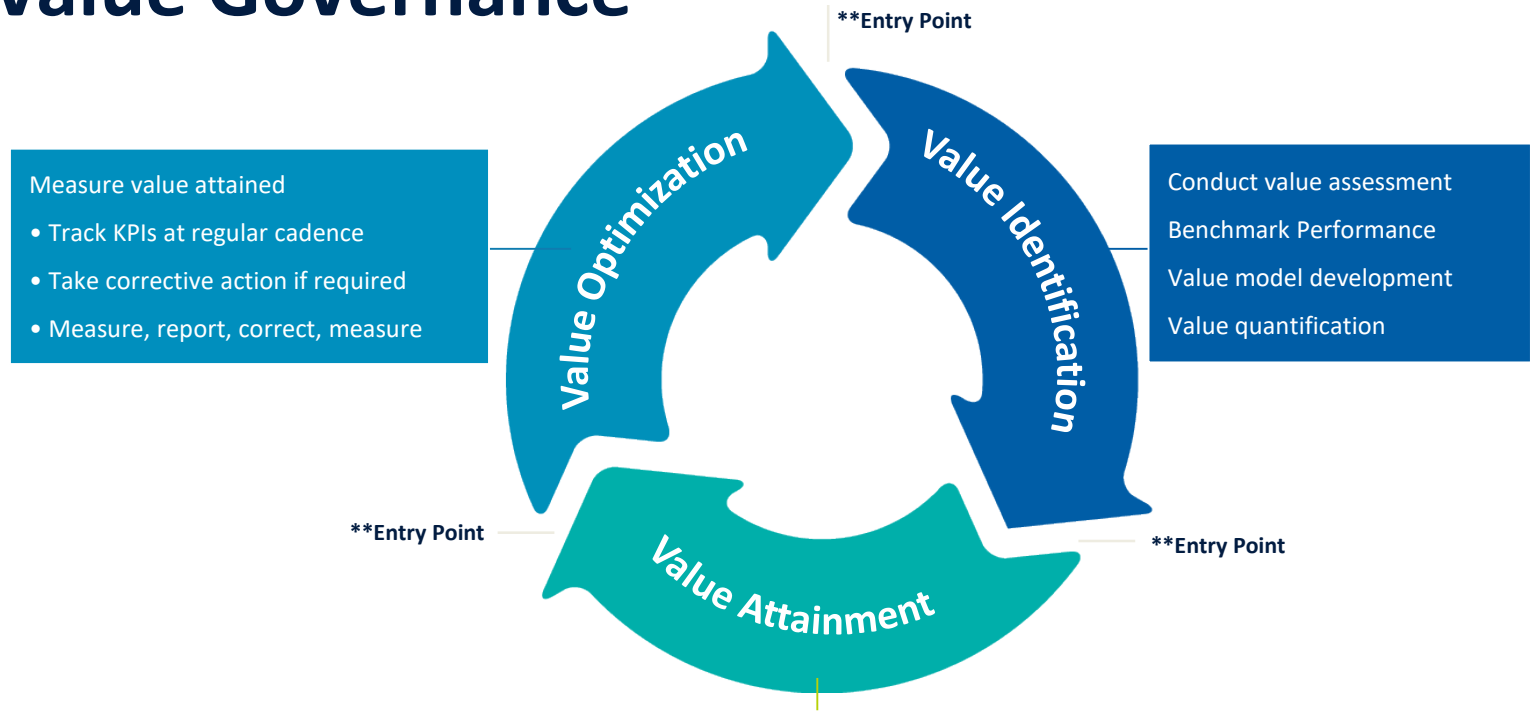
Decide Change Approach
Rewards and incentives for compliance and commitment

Program Structure

- “Best Practices” Approach to maximizing the value of each workstream
- Executive Alignment & Commitment
- Blended team with single accountability

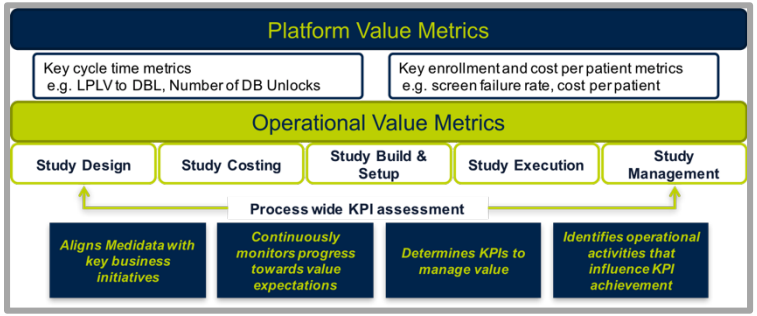


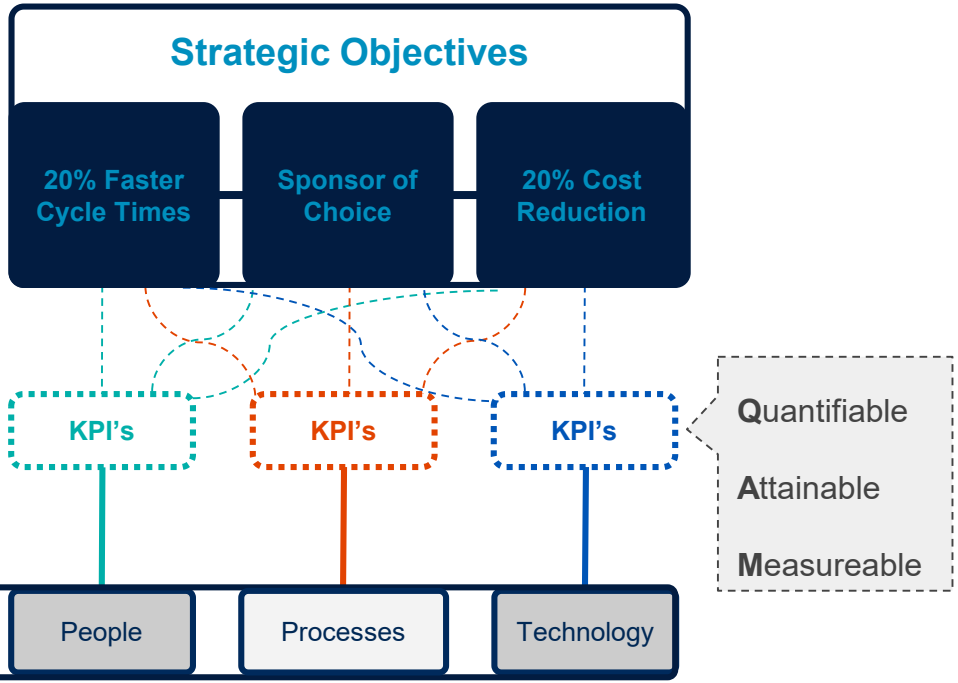
Value Governance



Note: **Entry Point denotes different points at which Sponsors/CROs can enter the value lifecycle

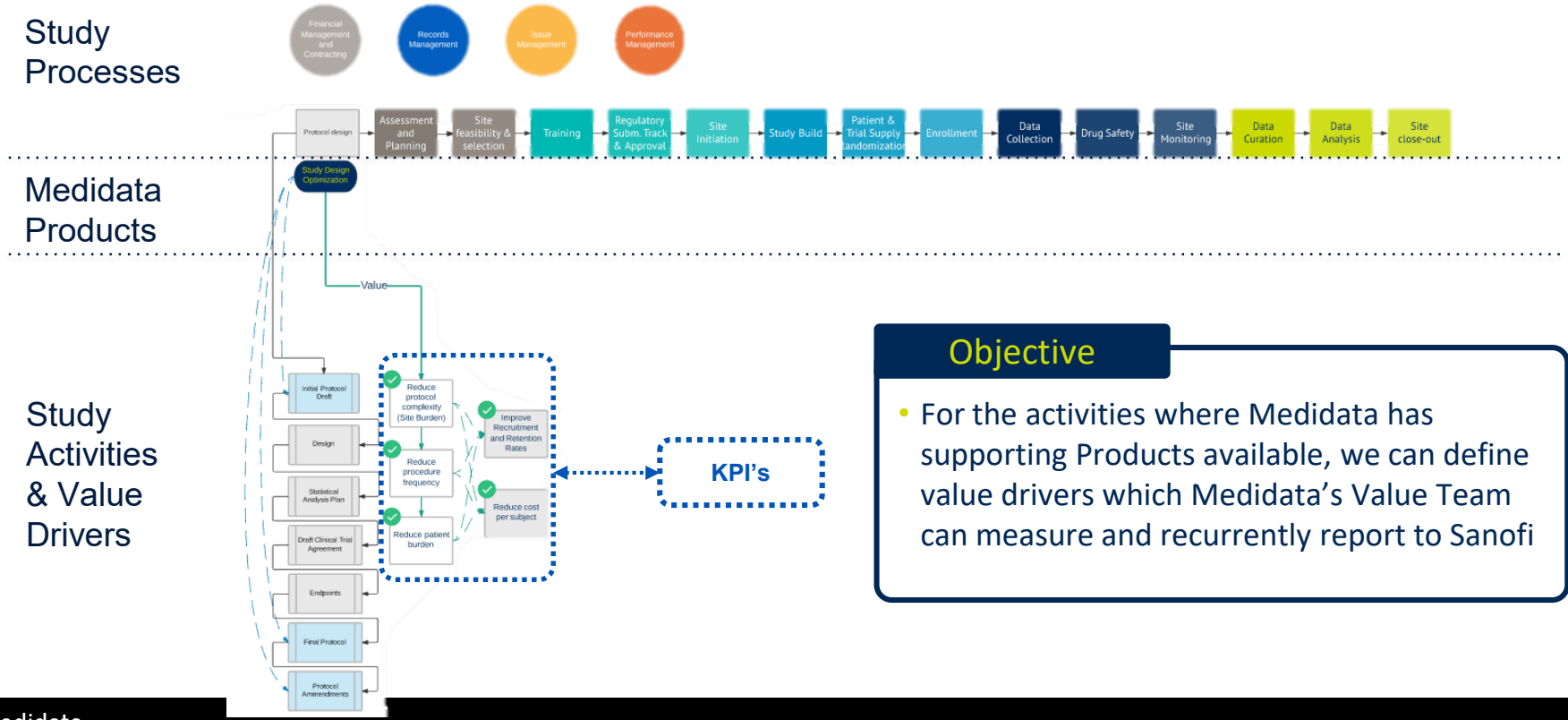
Value Governance (How)





Example - Medidata products supporting value drivers and KPI's

Study Design



Objective

- For the activities where Medidata has supporting Products available, we can define value drivers which Medidata's Value Team can measure and recurrently report to Sanofi

RAVE ENROLL – VALUE DRIVERS

Patient
Centric

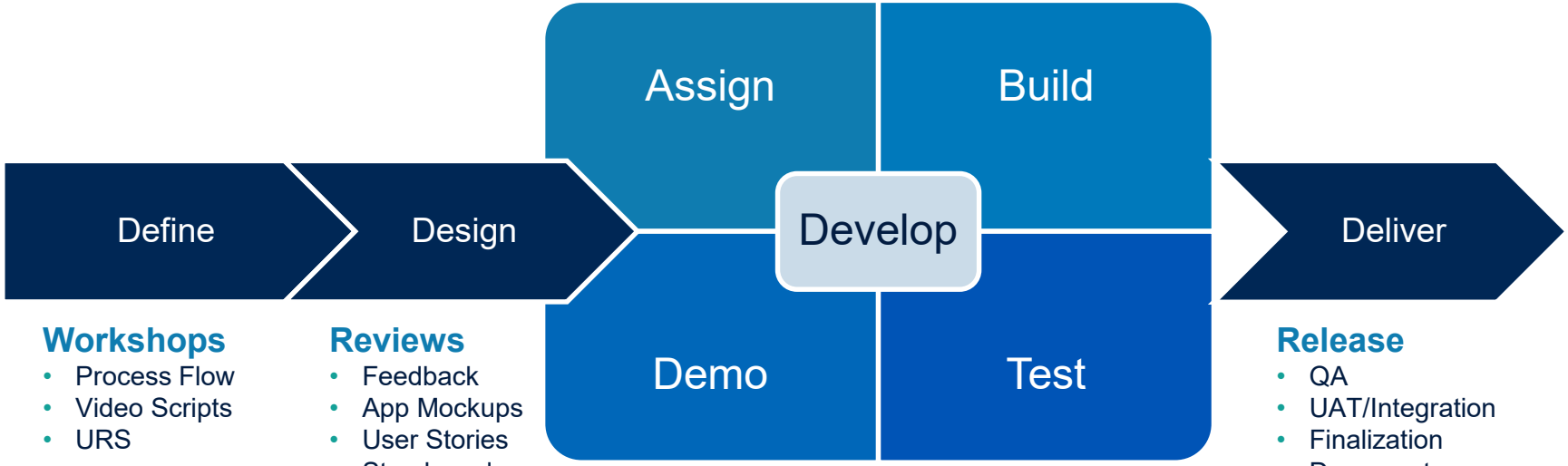
Efficient
Trials

Faster Study
Start up

Reduced
Study Risk

Integrated
Platform

Professional Services Configuration



Workshops
- Process Flow
- Video Scripts
- URS

Reviews
- Feedback
- App Mockups
- User Stories
- Storyboards
- Integration

Approval
- Feedback
- Application Design
- Configuration

Release
- QA
- UAT/Integration
- Finalization
- Document
- Go-Live

(5-12 weeks)

MIT Processes are Enablers for Your Success

Leveraging Technology, Expertise and Optimized Process to Move Quickly, Efficiently and Collaboratively

Reduce Risk

- Collaborative Project Management
- Interactive Technologies like Smartsheet providing real-time project schedule updates
- Optimize your processes leveraging Best Practices
- Define your success factors & performance measures

Save Time

- Proven, Evolving and Innovative Methodology
- Enables rapid configuration of Medidata Platform
- Guiding principles with touchpoints through engagement
- Leverage Rapid Study Builder to collect, record and approve user requirements

Expertise

- Unmatched Expertise and Experience: 420,000+ Study Sites
- Proven Best Practices to accelerate clinical trials and ensure high quality
- Subject Matter Experts on Medidata Platform and design across therapeutic areas