MEDIDATA

Digital Technology for Clinical Research

A Data-Driven Approach to Study Planning, Management, and Oversight

Simposio AFI 2021
Thursday 2nd December, 2021

DASSAULT SYSTEMES | The 3DEXPERIENCE® Company

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Today's Agenda

- Introduction to Medidata
- The Clinical Research Landscape
- The Evolution of Clinical Research Technologies
- Clinical Technology in the Age of COVID

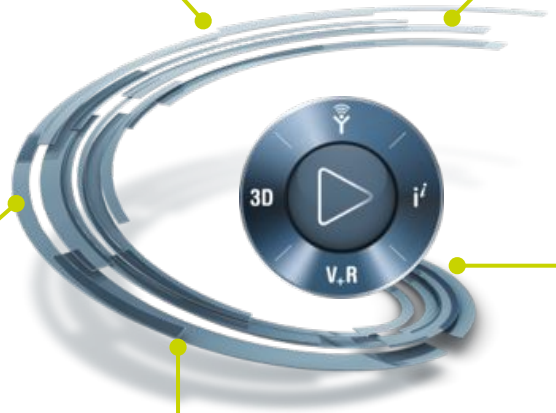
3DS Life Sciences Capabilities

4. MANUFACTURING

- Medical device tracking
- Improved supply management & logistics

5. COMMERCIALIZATION

- Data acquisition
- Health economic modeling
- Virtual surgery



3. CLINICAL DEVELOPMENT

- SaaS for Phase I-IV Clinical Trials across all therapeutic areas
- Focus on Data Management, Clinical Operations, Patient Experience and Advanced Analytics

1. RESEARCH & DISCOVERY

- Closing the Loop: RWD, RWE, & mod/sim for drug design
- Drug repurposing

2. PRECLINICAL DEVELOPMENT

- Material Management & Inventory
- Lab + Patient + Clinical Data to improve go/no go decisions

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Medidata Mission

Together, we power smarter treatments and healthier people


7,000,000
Patients and Healthy Volunteers

Solutions to Address All Your Clinical Technology Needs

patientcloud | Rave | acornai

Patient Data Capture

Decentralized Clinical Trials Program

eCOA

eConsent

myMedidata

- LIVE (video visits)
- Registries

Sensor Cloud

Data Management

Rave EDC

Coder

Imaging

RTSM

Safety Gateway

Site Cloud: End of Study

Clinical Operations

Adjudicate

CTMS

Decentralized Clinical Trials Program

eTMF

Financial Management

- Grants Manager
- Site Payments

Planning

- Design Optimizer
- Medidata Designer

RBQM

- Detect
- Remote Source Review
- Risk Management
- Targeted SDV

Advanced Data and Analytics

Integrated Evidence

- Synthetic Control Arm®
- Trial Design
- Medidata Link

Intelligent Trials

- Performance Analytics
- Study Feasibility

Commercial Data Solutions*

Connected Patient*

*Commercial Solution

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COVID-19

Partner to the Industry

445+
Studies

450K+ (775K+ projected)
Patients

216
Sponsors

81
Countries with Active Sites and Patients

Builds in 2-4 Weeks
Using Rave and Patient Cloud Solutions

5B+ Records from 250M+ Patients
On Our Real World Evidence Environment

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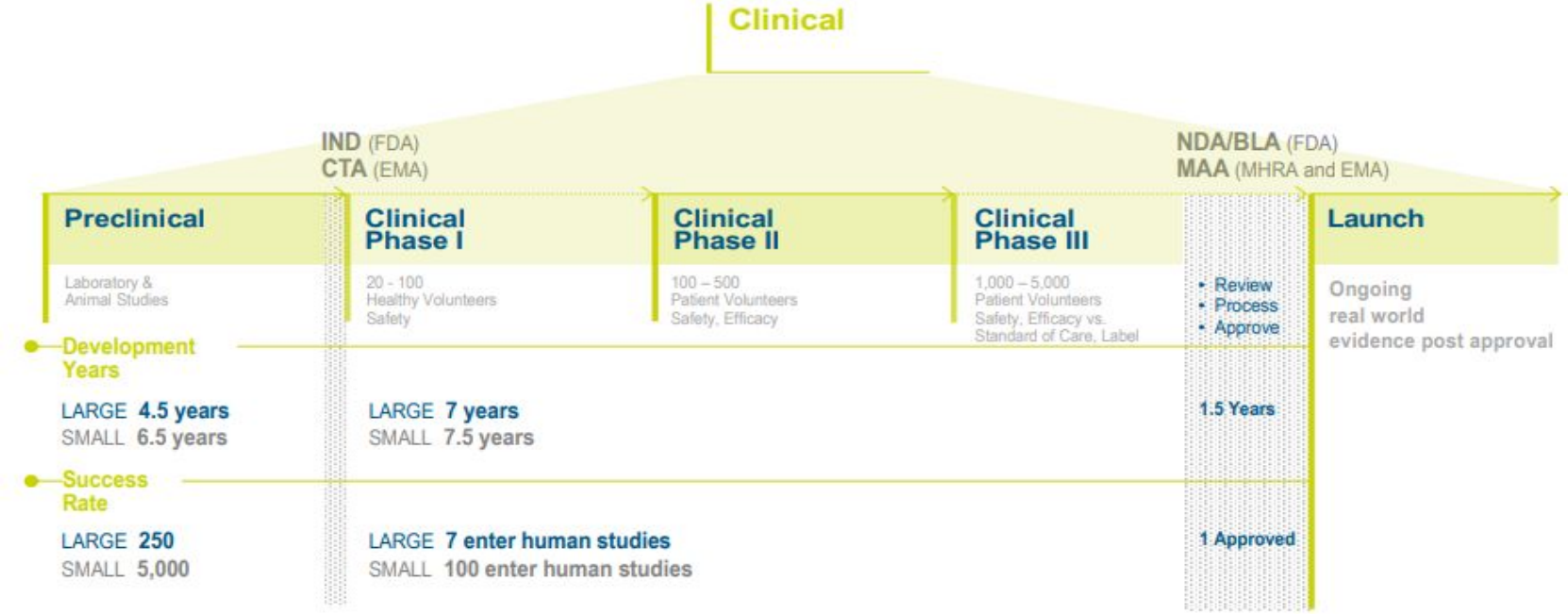
Phases of Clinical Development



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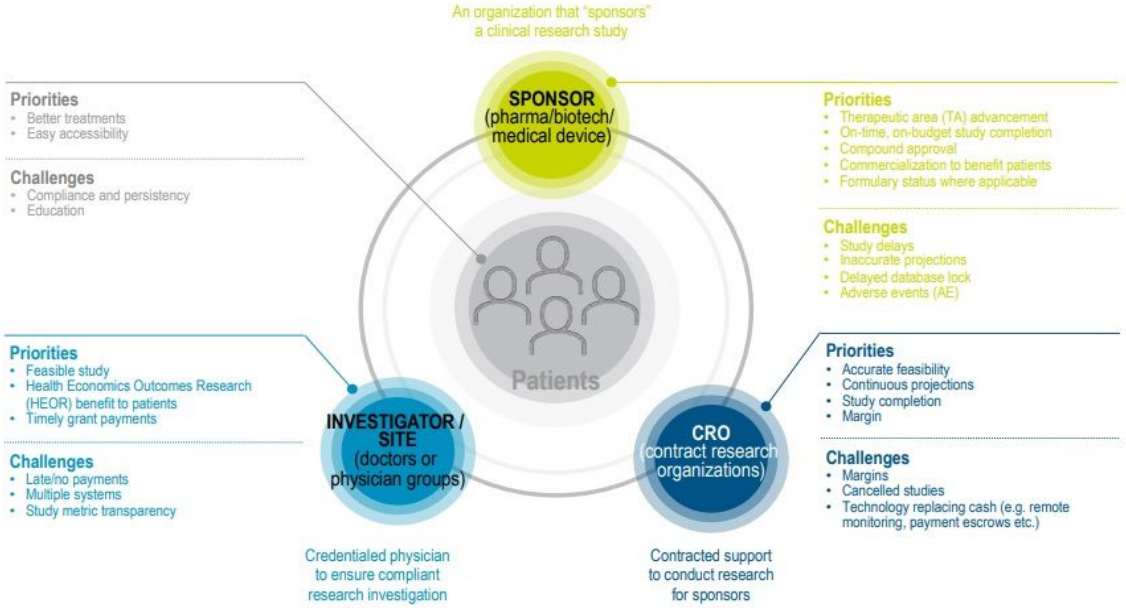
Clinical Trial Ecosystem



Technology Companies like Medidata Coordinate and Accelerate Process and Collaboration Across Stakeholders

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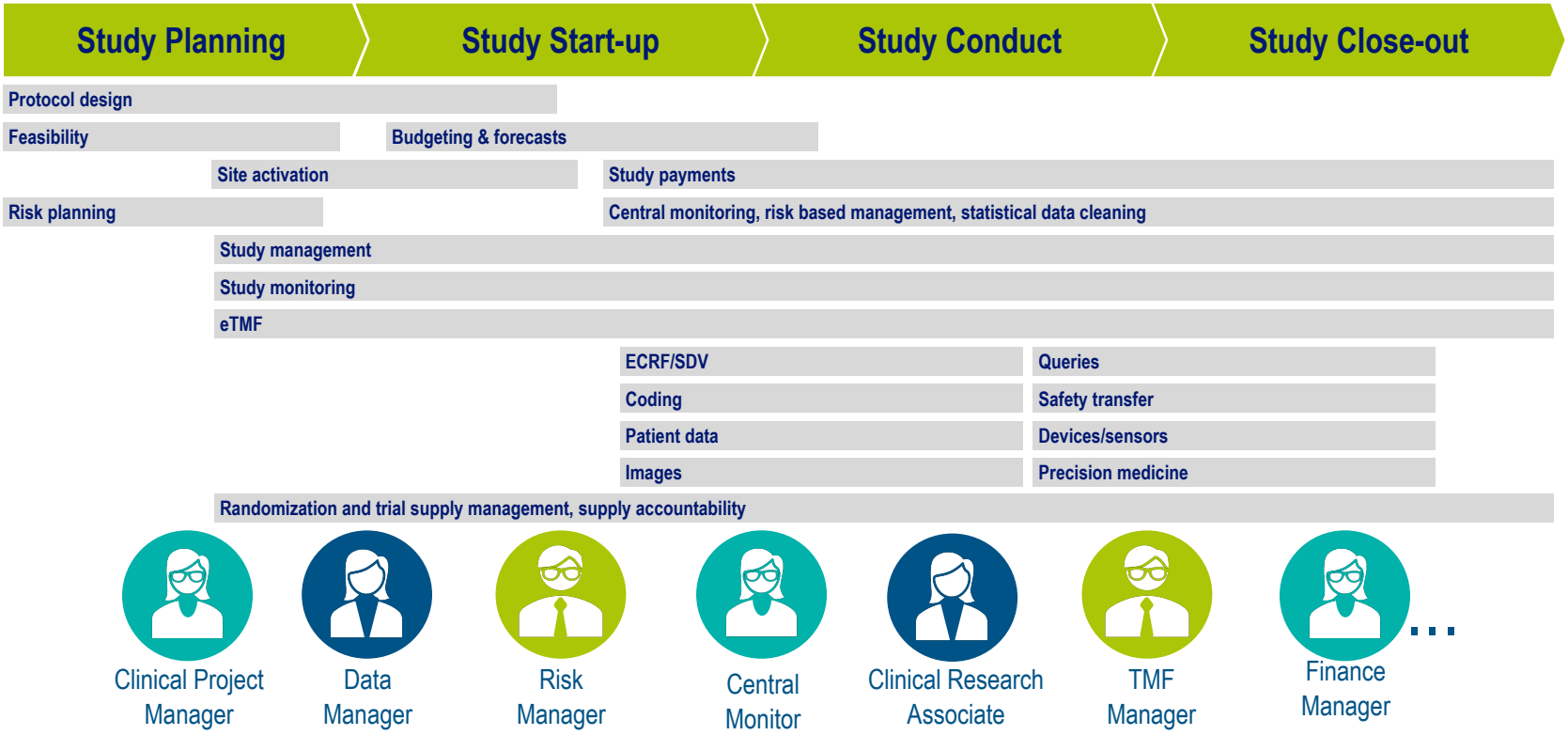
Traditional Systems and Stakeholders Required to Execute Clinical Trials



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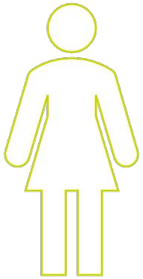
The Clinical Data Landscape Has Changed

Exponential Increase in Data Volume, Velocity and Complexity

Data volume has **increased 7x** in the last 20+ years[1]
Addition of new data sources and exploration of novel endpoints

Complex Web of Systems and Roles to Collect and Analyze Data

25+ different systems used within a single clinical trial[1]
Evolution of roles that use technology and how new tools are utilized



More Data Coming Directly From Patient

Patient reported data is becoming **more prevalent**
New devices to collect and monitor patient data should prove parity with traditional methods

[1]Average number of data points in Phase 3 Pivotal trials. 2001-2005 - 0.5 Million. 2015-2020 - 3.5 Million. Source: Tufts CSDD 2020 (data is pre-pandemic)

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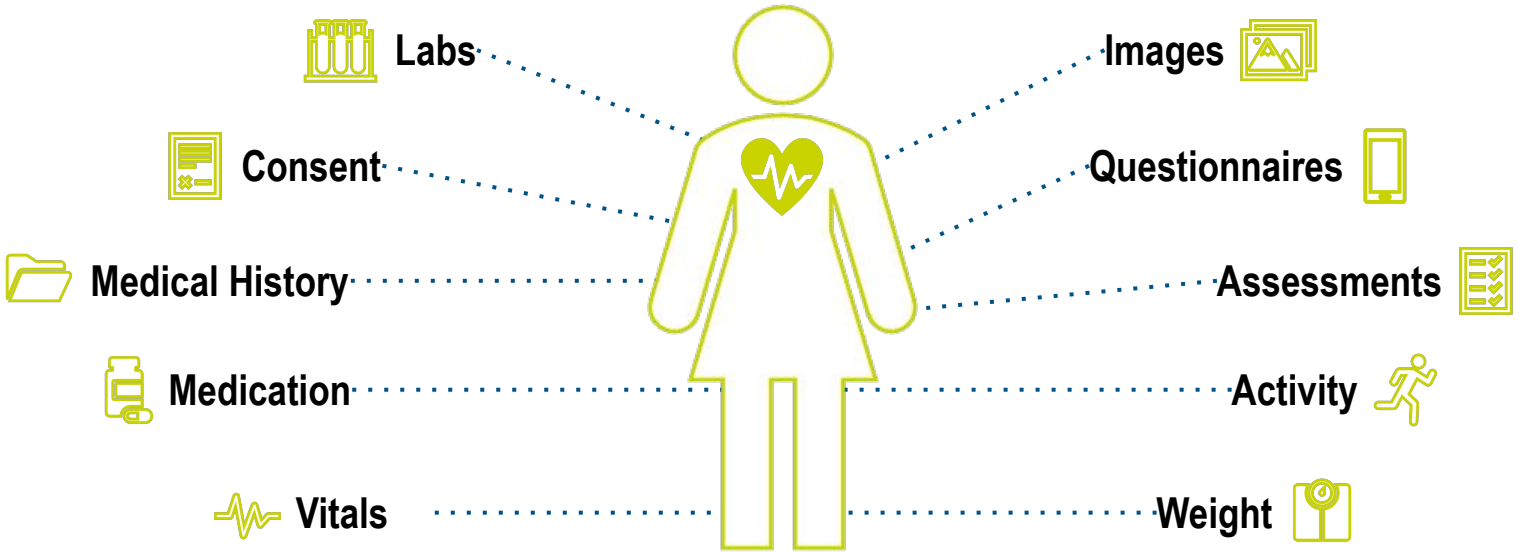
We Are Collecting More Patient Data Than Ever Before



How to Reconcile Divergent Data for a 360° View of the Patient?

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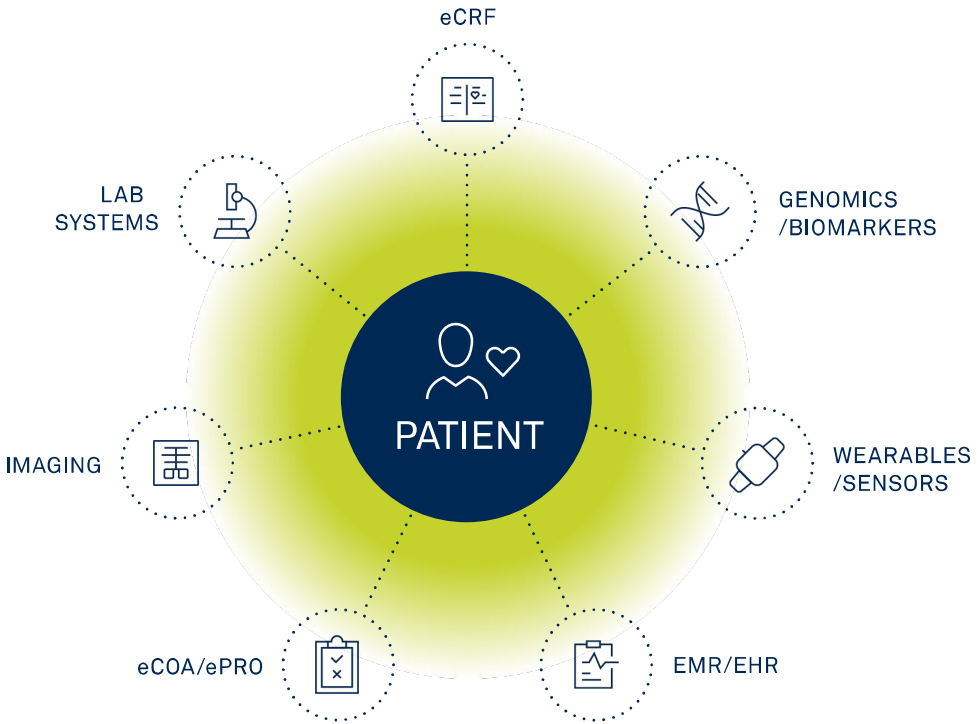
Modern Challenges of Clinical Research

- Data ingestion, processing, standardization - new data does not fit into existing standards
- Monitoring and oversight of data collection - making sense of new data and ensuring robustness and consistency. Traditional methods are impractical or obsolete
- Ensuring parity of new data collection models and continuing to provide highest level of patient safety



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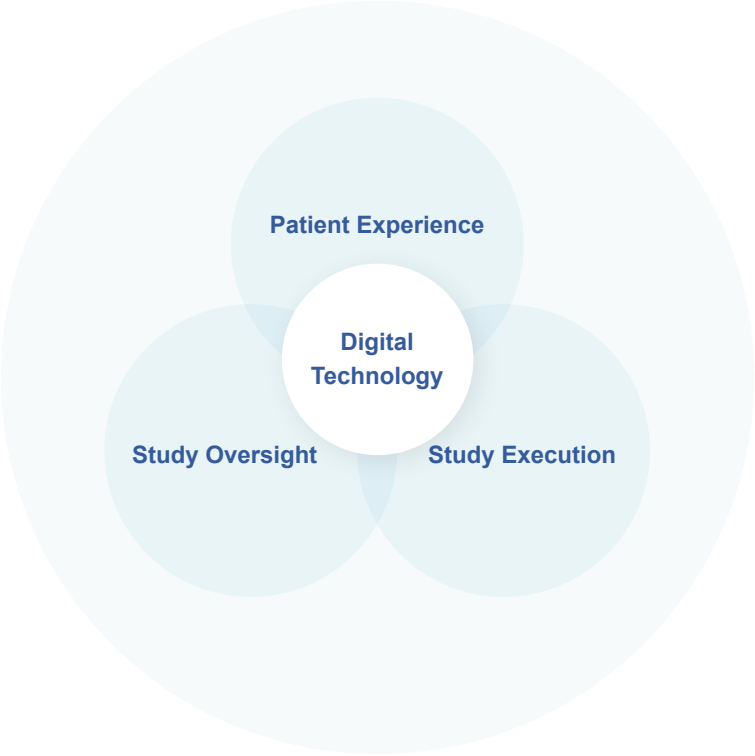
Digital Technology Transforms the Clinical Trial Paradigm

- ✔ **Engage patients,** where they are at
- ✔ **Ensure compliance** and patient understanding
- ✔ **Aggregate data** into a complete dataset
- ✔ **Surface insights** with analytics and AI/machine learning
- ✔ **Continuously monitor** patient and study data
- ✔ **Optimize** physical and virtual interactions with sites and patients



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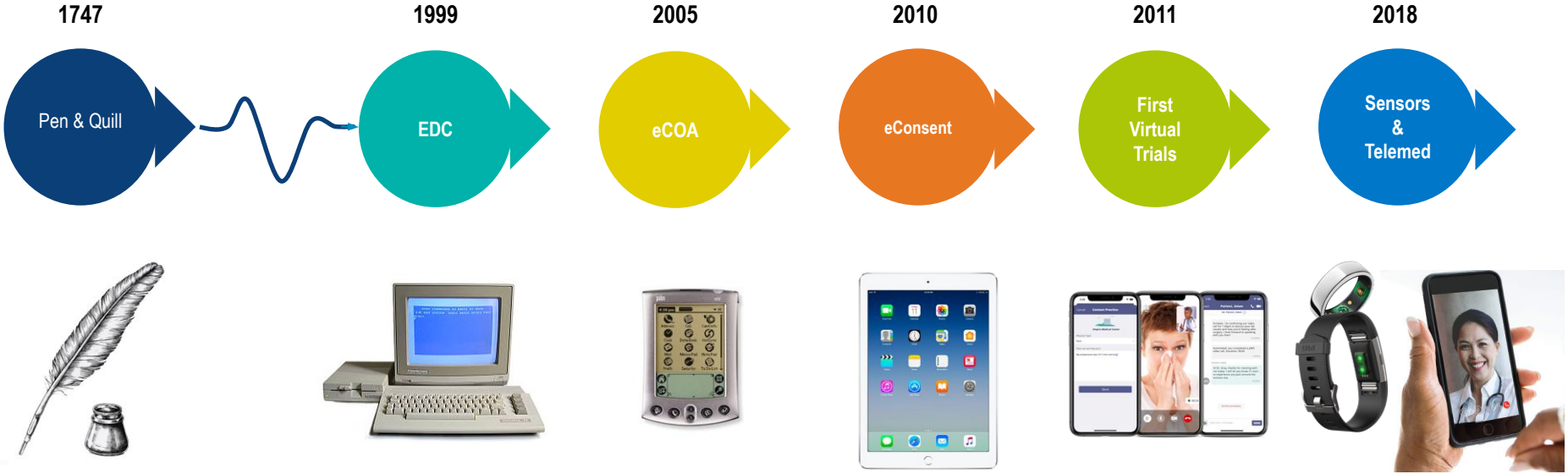
Clinical Data Capture Evolution



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Sensor Cloud Devices and Usage

INTEGRATED

BioIntellisense

MC10 Biostamp

Actigraph

Biobeat

Oxitone

Nuvoair

Sensor data usage

2019: 10-15%

2025: expected 70%

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The Value of a Sensor Data Platform

PATIENTS

Reduces patient burden

- Reduce site visits, time, travel and inconvenience
- Provide non-invasive methods of collecting data

SPONSORS

More precise continuous data, lower cost, greater efficiency

- Objective measures can enhance more subjective ePRO/eCOA data
- Faster trials with higher success rates

PARTNERS/ ECOSYSTEM

Unified platform for insight development

- Common data model
- Build new measures & digital endpoints
- Assess data against data measured in clinic

SITES

Opportunity to focus more on patient care

- Early compliance and treatment response indicators
- Efficiencies in same interfaces, log-ins and workflows

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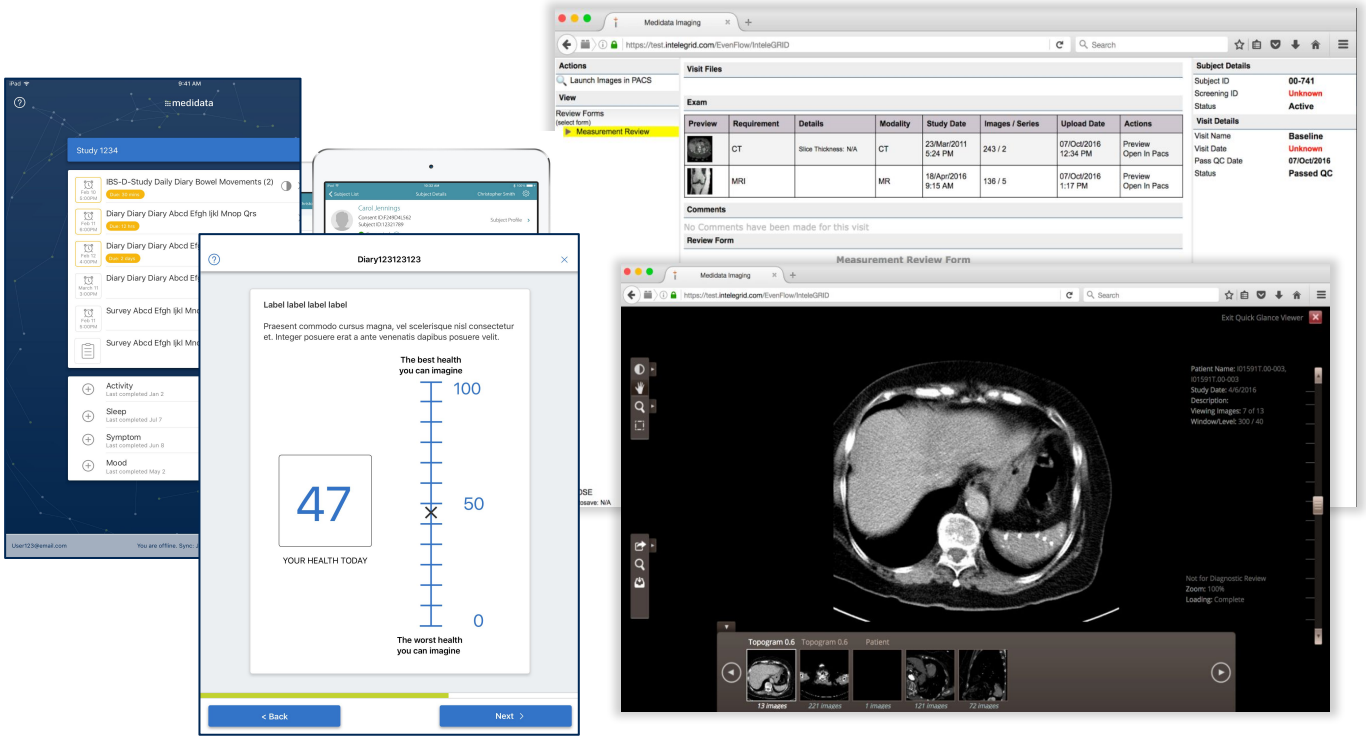
Automating Intelligent Imaging Workflows

- Intelligent Assessment Workflows
- Flexible Image Review Tools
- Unprecedented Visibility
- Advanced Reporting Engine



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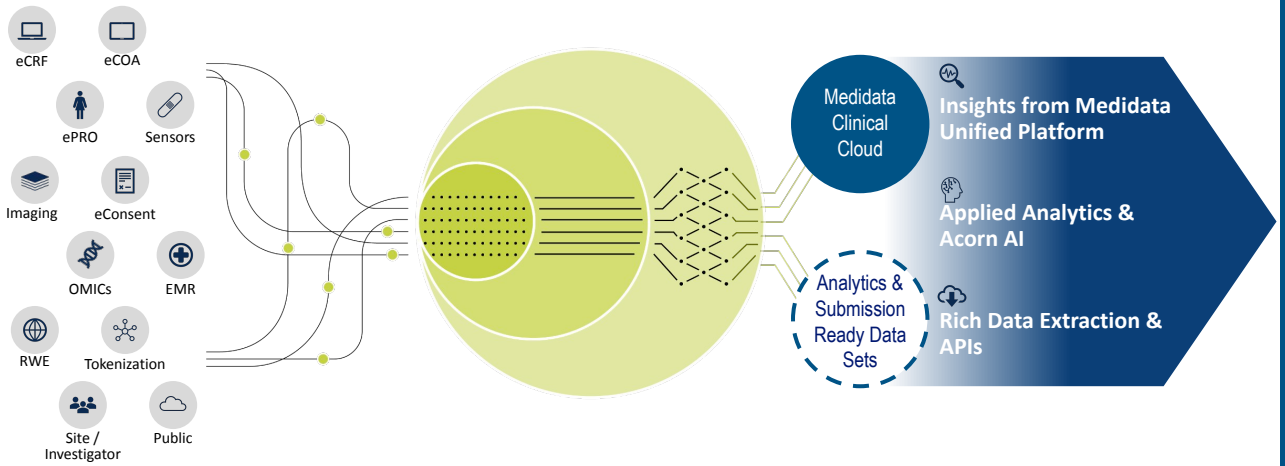
Clinical Data Platforms Must Aggregate ALL Data



INGEST

Flexible, purpose built ingestion from different data sources and different shapes

STANDARDIZE

Data linked to studies, patients, visits and standardized to common data models

ANALYZE

World class platform capabilities building 360° view of the patients and your portfolio from startup through execution, oversight, and submission

Impact

- Seamless integration on data regardless of source
- Data kept in submission- ready format for easy review and analysis
- Tools for next level analytics - trial design, safety and efficacy analysis, quality and risk management, etc.

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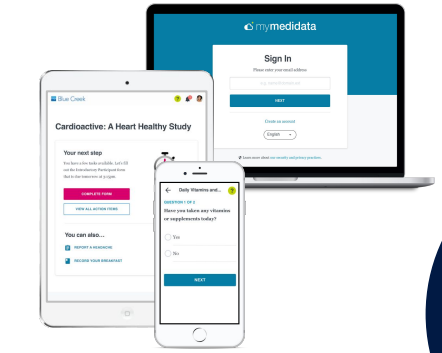
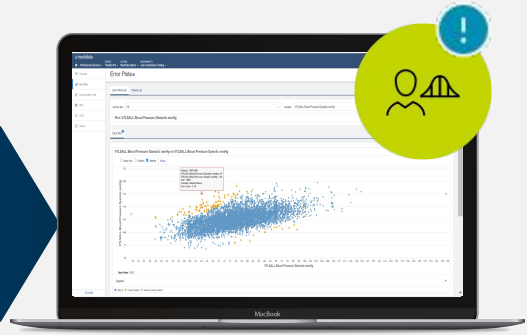
Analytics To Continually Monitor All Data

Identify Issues Early



Patient data collected on single platform

ADVANCED ANALYTICS TO CONTINUALLY ANALYZE DATA



Automatic notification when to take action

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Centralized Monitoring Tool - Comprehensive Data and Risk Surveillance

- **End to end data surveillance** – data review for Data Managers, safety monitoring for Medics, site performance oversight via KRIs for Monitors, advanced analytics for Centralized Monitors and study level insights via QTLs for Project leads
- **All data in one place in near real time** – unique ability to ingest and aggregate subject level data from almost any source
- Analyses linked to data and actions - **integrated workflows**
- A **unified approach to decentralized trials**, from critical data & process risk management, through modern data acquisition, digital oversight & anomaly detection, to support remote monitoring capabilities

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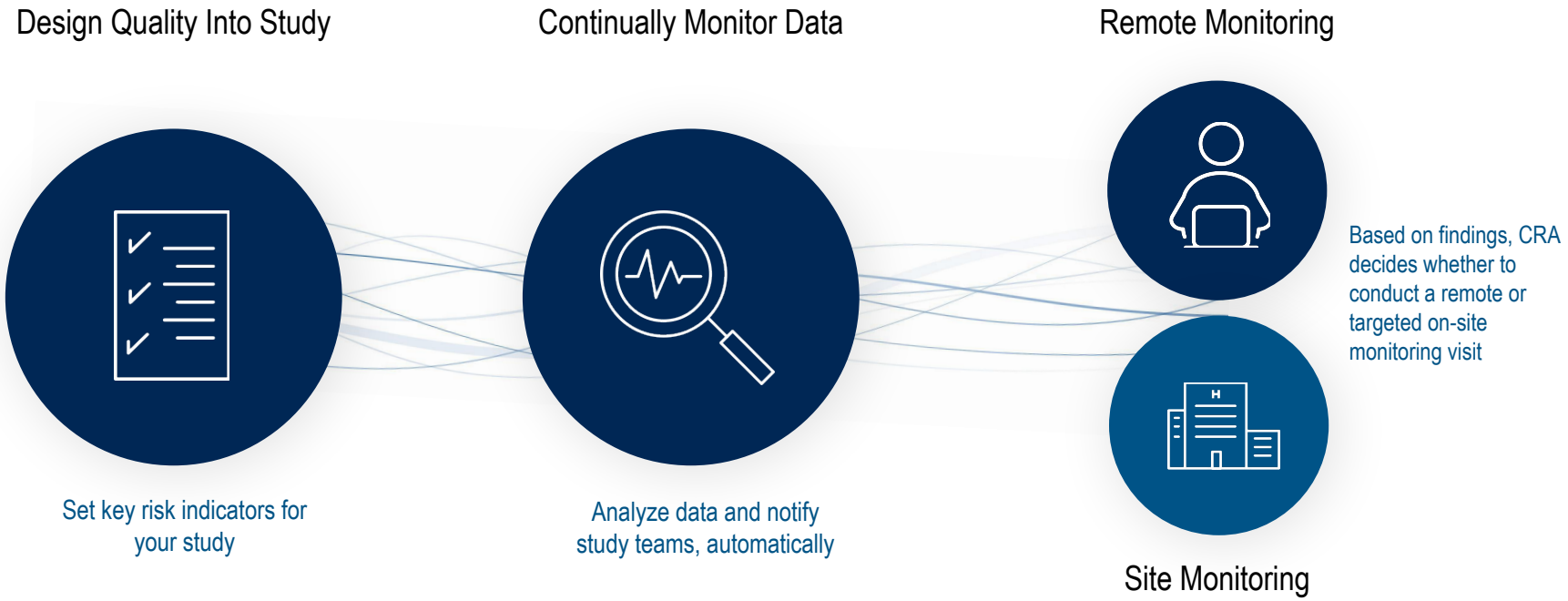
Flexible Approach to Decentralized Monitoring Workflows



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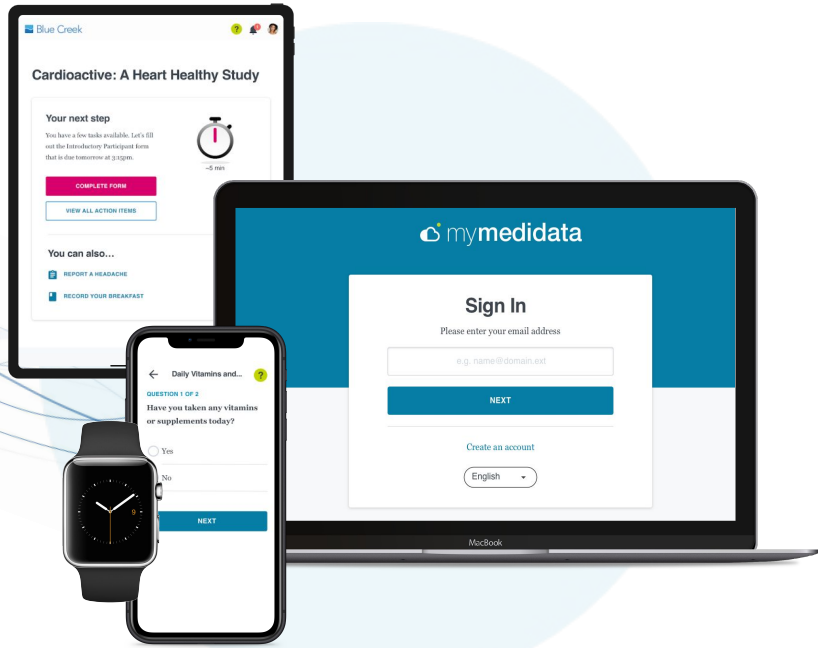
A Single Technology Platform For Fully Decentralized Trials

Patients Engage With Trial
Where They Are



A Single Platform For….

- Electronic Data Capture
- eConsent
- eCOA
- Sensors
- Video Visits
- Registries
- Direct-to-Patient Shipments

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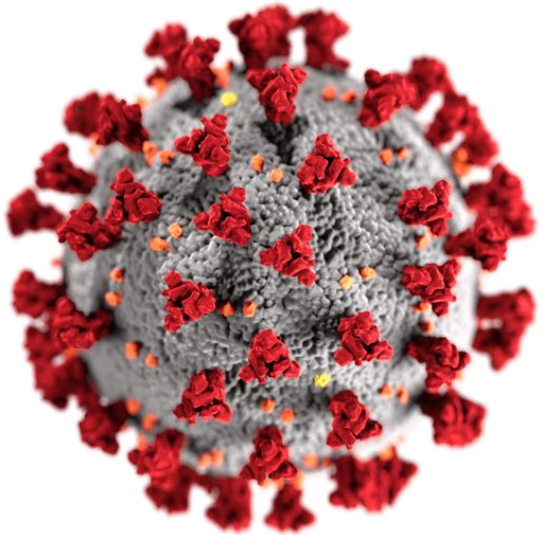
Clinical Technology in the Age of COVID

Pandemic Strategies

- Heightened Awareness of Change
  - Sponsors and CROs seeking options
  - Patient Safety & Data Integrity
  - Discussion by regulators and industry
- Rapid Global Regulatory Response
  - FDA
  - EMA
  - MHRA
  - Sundhedsstyrelsen
  - ANSM
  - BfArM
  - HPRA
  - AIFA
  - CCMO
  - Swissmedic
  - TMMDA
  - HealthCanada
  - DoH
  - PMDA
  - HAS
  - MFDS



https://www.medidata.com/en/blog/covid-19-regulatory-developments-and-technology-use-in-clinical-trials/

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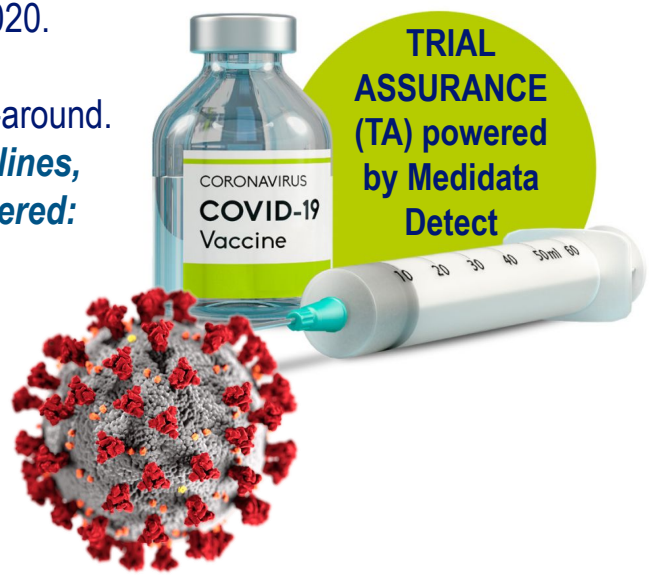
Running a Pivotal COVID-19 Trial

- Case Study: Medidata collaboration with a biopharmaceutical leader

Medidata Detect played a critical role in the sponsor's ability to advance the Phase III COVID-19 trial and achieve Emergency Use Authorization (EUA) in Dec 2020.

The urgency of the Phase III COVID-19 trial demanded success on the first go-around. In partnership with the sponsor, Medidata achieved ***new standards for timelines, unimaginable scale and revolutionized clinical trial execution and delivered:***

SPEED OF EXECUTION	SITE CENTRICITY	PATIENT CENTRICITY	DATA MGMT. EFFICIENCY



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New Standard for Go-Live

How was this achieved?

Through thoroughly understanding critical elements of complex trial design

Why is this important?

The first step in the process was record-breaking deployment timeframe

Rapid deployment meant faster diagnosis of data quality, query resolution, and database lock

Key Facts:

- 1st TA readout: Analyzed 25K subjects across 98 sites with 28M+ data points
- 2nd TA readout: Analyzed 30K subjects across 99 sites with 47M+ data points

Outcomes:

14 days

From First Patient First Visit (FPFV) to System Live
FPFV = 7/28/2020; System Live = 8/14/2020

66% faster than industry average of 6 weeks

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Unmatched Speed of Execution

How was this achieved?

Through standardizing design, automated daily dataflow from variety of sources

Why is this important?

Sponsor was able to diagnose data quality issues, avoid new issues, respond to evolving milestones and resolve queries faster

	Benchmark	Contracted	Latest
Detect – Time to Go-live	6 weeks	2 weeks	1 week
TA – Lead Time	6 weeks	4 weeks	2 weeks
TA – Analysis Time	2 weeks	2 weeks	1 week
Data Refresh Frequency	Monthly	Weekly	Daily

2X Faster Vs. Contracted

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Unprecedented Site Centricity

How was this achieved?

Through training sites and providing them with very specific actions to be taken

Key Observation:

TA identified sites that were under reporting Adverse Events (AEs)

Why is this important?

Under reported AE levels would be discovered much later in the study execution process delaying the database lock

Outcome:

Faster issue identification, response and resolution allowing for better efficiency and lower site burden

Estimated Impact:

Sites execute faster when they're provided with specific actions that need to be addressed at a patient level

40-45% Faster

(Validation in progress with Sponsor)

Pioneering Patient Centricity

How was this achieved?

Through ensuring diary compliance and accelerated resolution of safety concerns

Key Observation:

TA identified patient e-diary non-compliance

Why is this important?

Critical for identification of patient safety and centricity

Sponsor leveraged info from TA and worked with CROs to address safety concerns

Outcome:

- Patients impacted were identified as needing critical attention
- Sites were provided with specific patient level information and actions
- Specific guidance was given to resurrect e-diary compliance, patient safety and data quality
- Data integrity was not sacrificed even though vitals were collected remotely
- High impact to ensuring trial continuity / avoiding delays and patient safety

~95% Compliance Rate

(Validation in progress with Sponsor)

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