

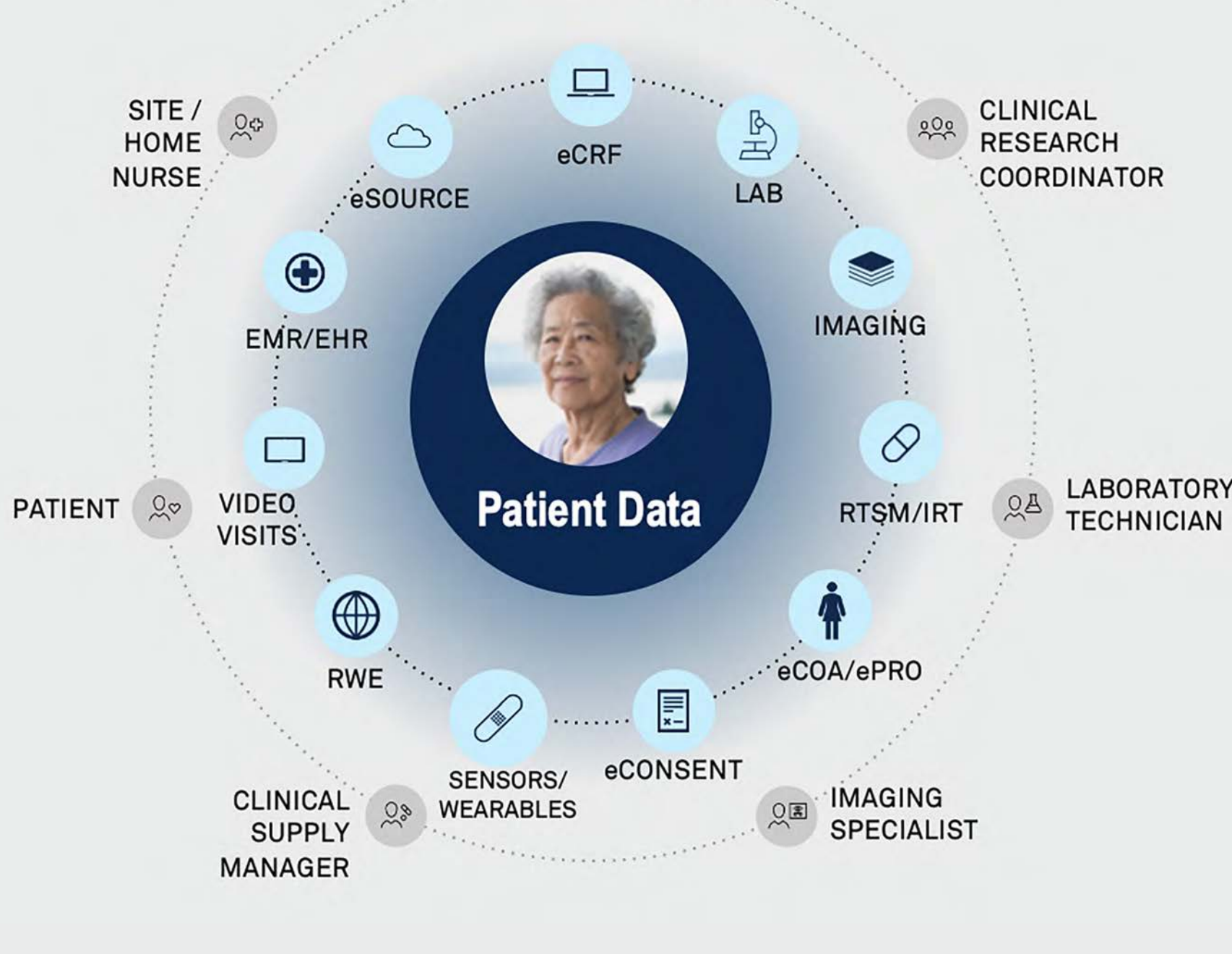
The Next-Generation of Clinical Data Management

The Clinical Data Landscape Has Changed

Clinical trial data volume has increased seven-fold in the last 20 years¹ to **3.6 million data points** in a typical Phase III study.¹

Only approximately 30% of clinical trial data is entered through eCRFs in EDC systems.²

More data is being captured directly from patients and from outside the clinical trial site, driven by the growth in decentralized trials.



¹ Average number of data points in Phase 3 Pivotal Trials, 2001-2005 - 0.5 Million, 2015-2020 - 3.5 Million. Source: Tufts CSDO 2021 (data is pre-pandemic).

² The Evolution of Clinical Data Management to Clinical Data Science: A Reflection Paper on the Impact of the Clinical Research industry trends on Clinical Data Management, 4 June 2019, <https://scdm.org/wp-content/uploads/2019/09/SCDM-Reflection-Paper-Evolution-to-Clinical-to-Data-Science.pdf>

...But Clinical Data Management Technologies and Processes Have Not Kept Pace

Aggregating and reconciling data from multiple sources takes huge effort.

An exhaustive point-by-point review of data cannot scale.

Database lock and data transformation into submission-ready outputs are too manual and take too long.

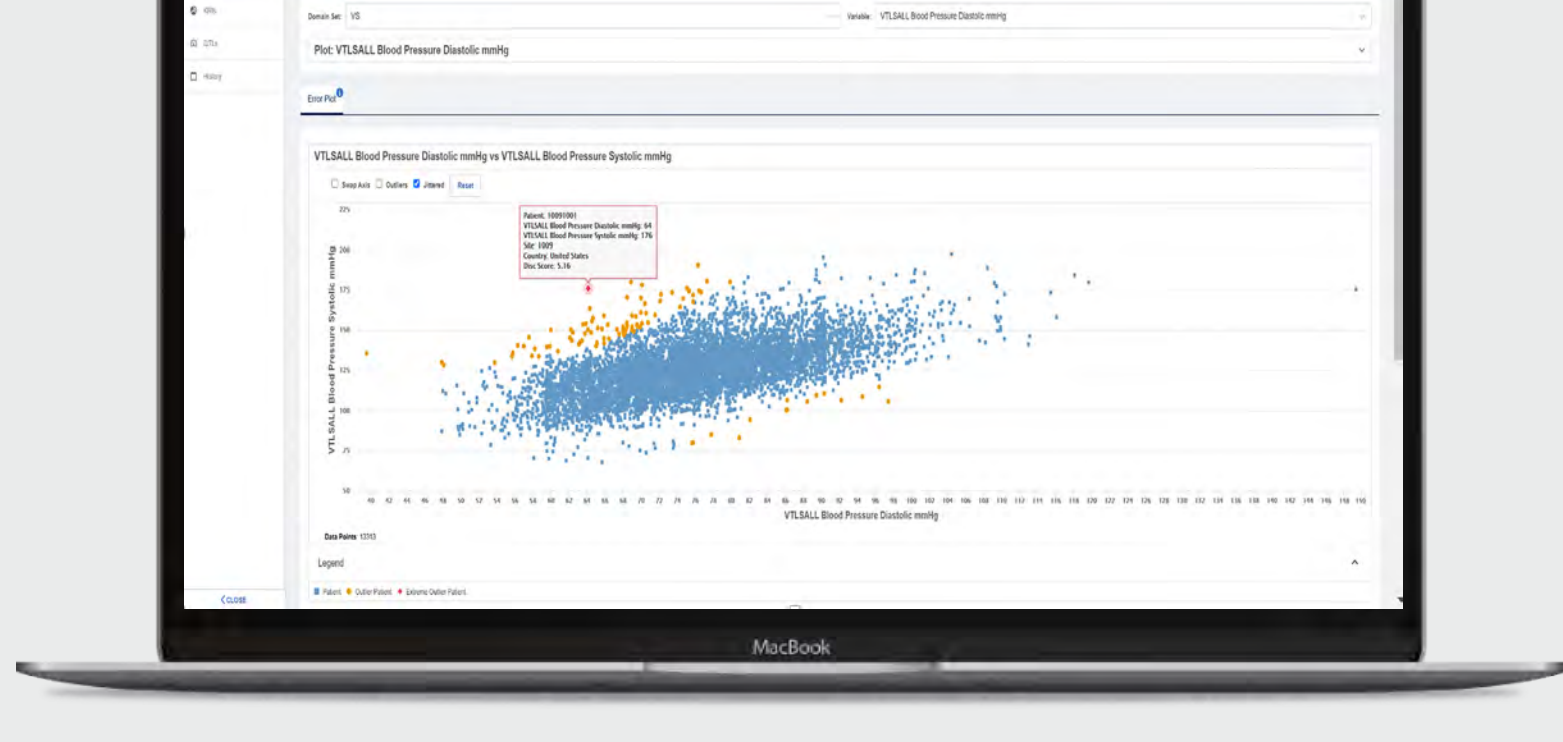
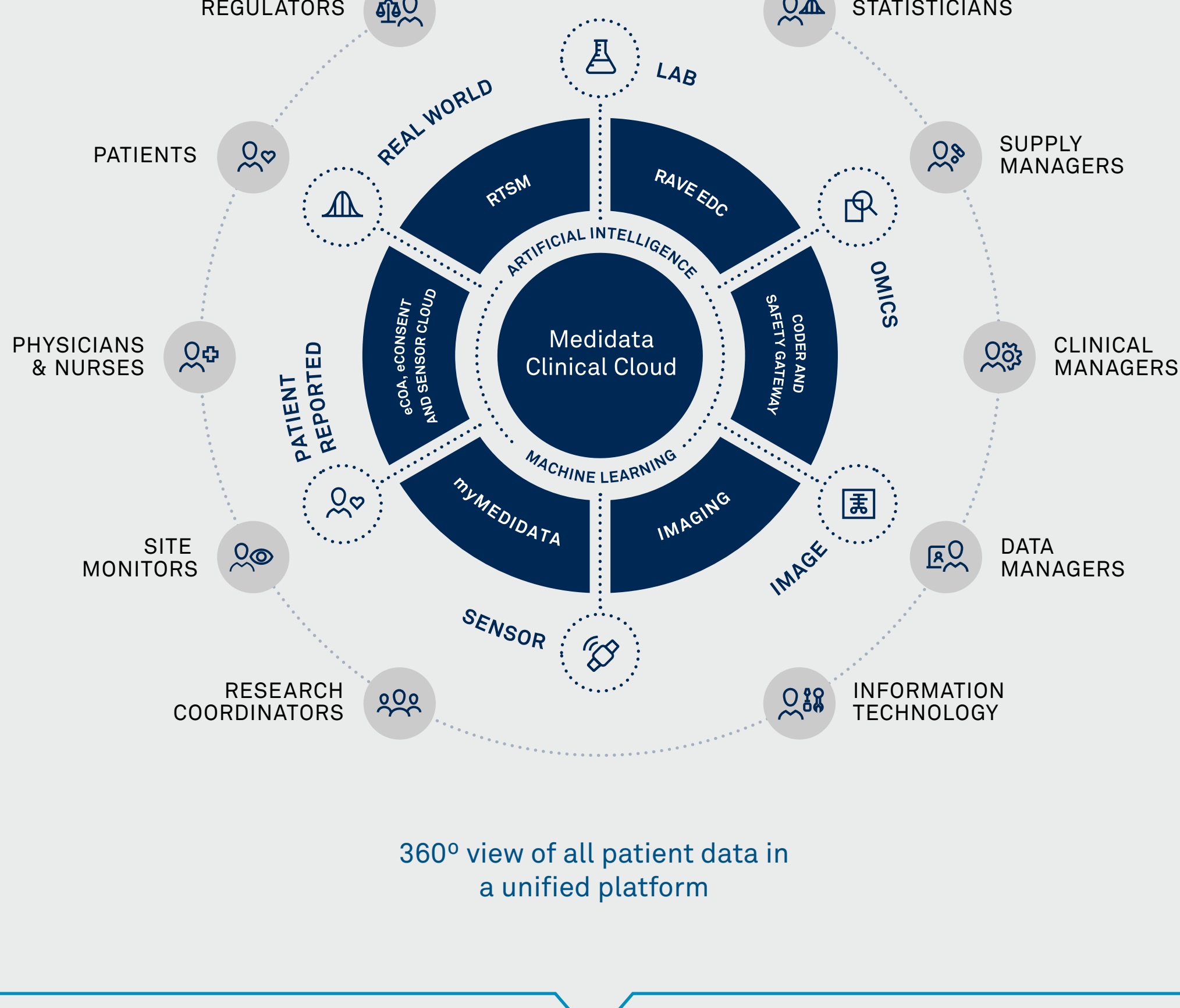
Integrating different data capture systems and their data is challenging.

Query-based data cleaning doesn't contribute proportionally to improving data quality.³

³ Risk-based Quality Management in CDM: An inquiry into the value of generalized query-based data cleaning, Journal of SCDM. Available at: <https://www.jscdm.org/article/id/20/>

Transforming Clinical Data Management Technology to Tackle the Evolving Data Landscape

So how do we modernize clinical data management technologies to manage the new and rapidly evolving data landscape?



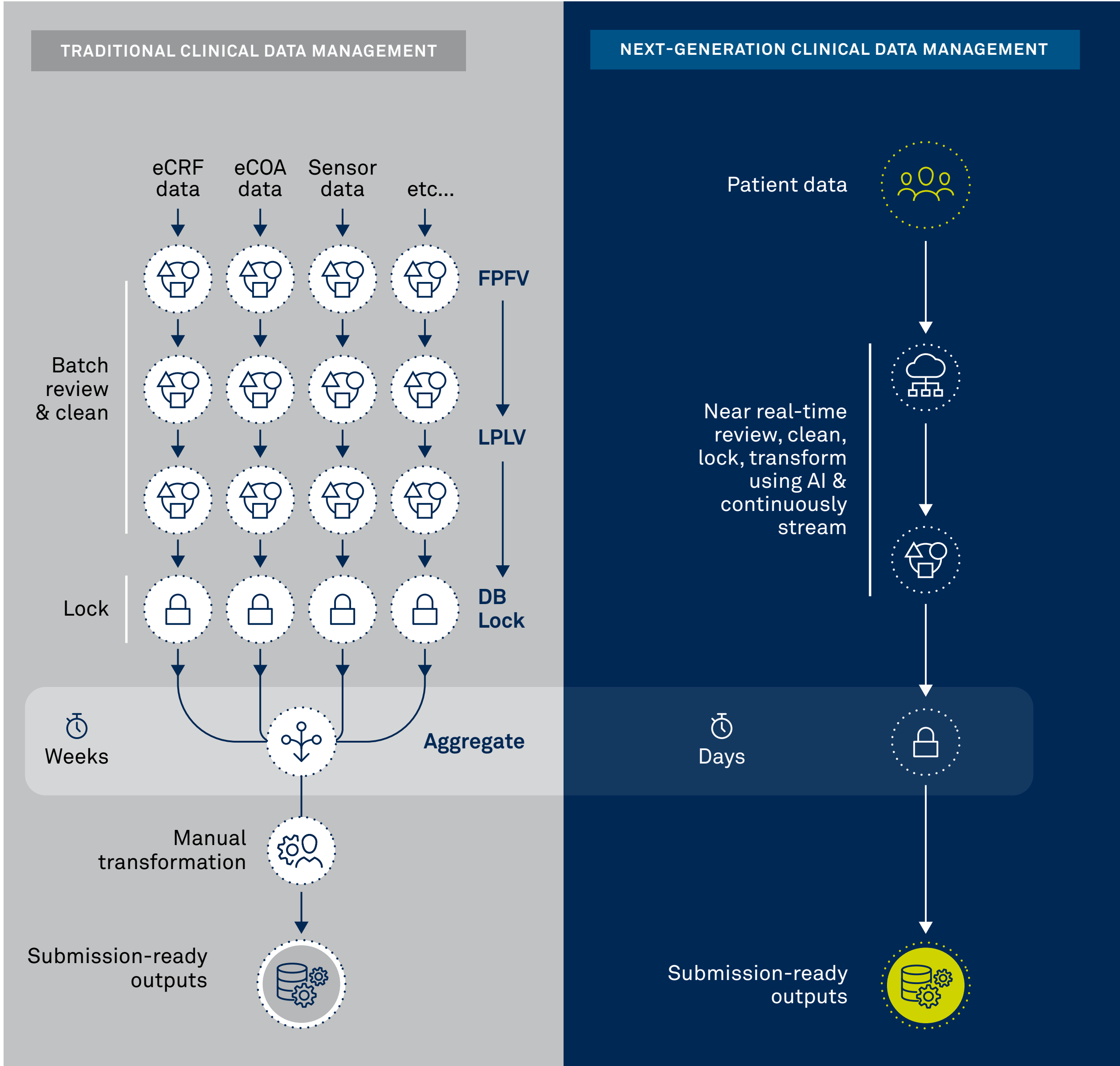
Real-time, automated data review using machine learning, analytics and visualizations



Automated, streamlined transformation of data for submission-ready outputs

Comparing Traditional and Next-Generation Clinical Data Management Approaches

New cloud-based platforms and intelligent data analytics will transform clinical data management processes.



Results Achieved by Medidata Customers

- Conduct studies **2 months faster**⁴
- Reach database lock **9 days sooner**⁵
- Reduce On-site Monitoring by **4 days** per site on each study using Rave EDC + TSDV (Targeted Source Data Verification)⁶
- Conduct **<50%** SDV (Source Data Verification) and maintain the same data quality with Rave EDC + TSDV⁷

⁴ Analysis of difference in median FPI to LPLV time for Rave EDC + at least one additional Medidata product vs. Rave EDC only studies (p<0.05) 2017 to 2021; Reduction of 59 Days.

⁵ Analysis of difference in median LPLV to DBL time for EDC + at least one additional product vs EDC only studies from 2017 to 2021.

⁶ Includes 241 studies per cohort. Statistically significant at *p<0.05 for comparison of means. Monitoring On-Site Rate defined as rate of on-site monitoring days per year across studies and sites for a study active period.

⁷ 12% lower average total query rate* in group using TSDV. Total Query Rate: # of Queries per 1000 datapoints. n=254 per group *p<0.05.

“With the Medidata Clinical Cloud™, we have a unified environment for reporting accurate data, reviewing data, and reporting accurate study results. It streamlines the study process for everyone involved—our team, sites, and patients.”

Erin O'Boyle
Head of Clinical Operations,
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