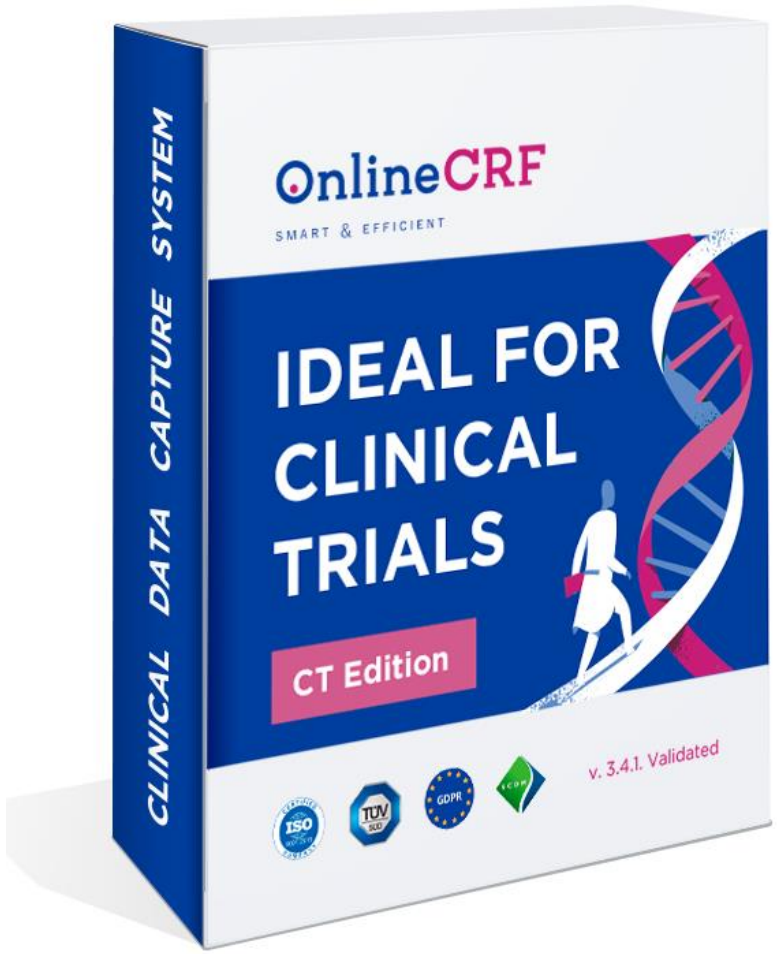
pharmaxi
SMART SOLUTIONS FOR PHARMACEUTICAL INDUSTRY

OnlineCRF
SMART & EFFICIENT

Електронні системи в клінічних дослідженнях. Очевидні здобутки цифрових технологій та перші нариси майбутніх перемог

Лебідь Ю.В.
Директор ТОВ «Фармаксі»

Pharmaxi has been developing EDC “OnlineCRF”



OnlineCRF complies with the industry standards

Сегодня поговорим о

- ✓Основные типы электронных систем, которые заслужили признание в клинических исследованиях
- ✓Что такое RWE и как RWE дополняет CT
- ✓Risk Based Monitoring
- ✓Будущее: AI, Blockchain, Wearable devices

C-Suite Survey Underscores Digital Technology's Growing Role in Clinical Trials

Findings from the most recent Biopharma Confidence Index show that the pandemic has substantially influenced biopharma executives' expectations in key areas like artificial intelligence/machine learning and real-world evidence.

The BCI is designed to measure the confidence of the industry's C-Suite and executive leadership. Respondents represent biopharma companies with facilities in the United States, Europe, and the Asia-Pacific region. The survey includes 259 questions about six key business indicators: capital markets, deal landscape, clinical development, regulatory affairs, commercialization, and business model and workforce.

Source: C-Suite Survey Underscores Digital Technology's Growing Role in Clinical Trials

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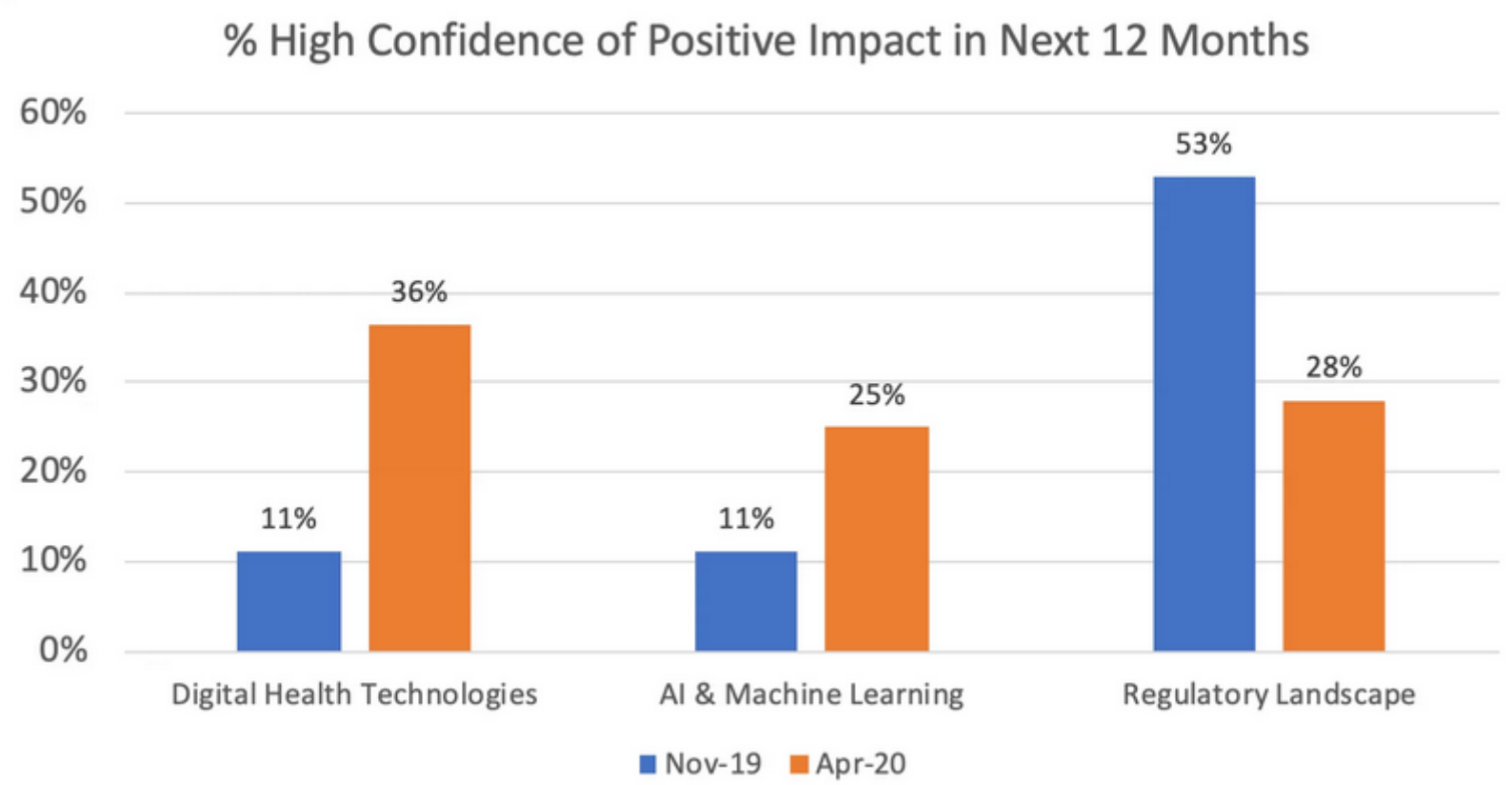

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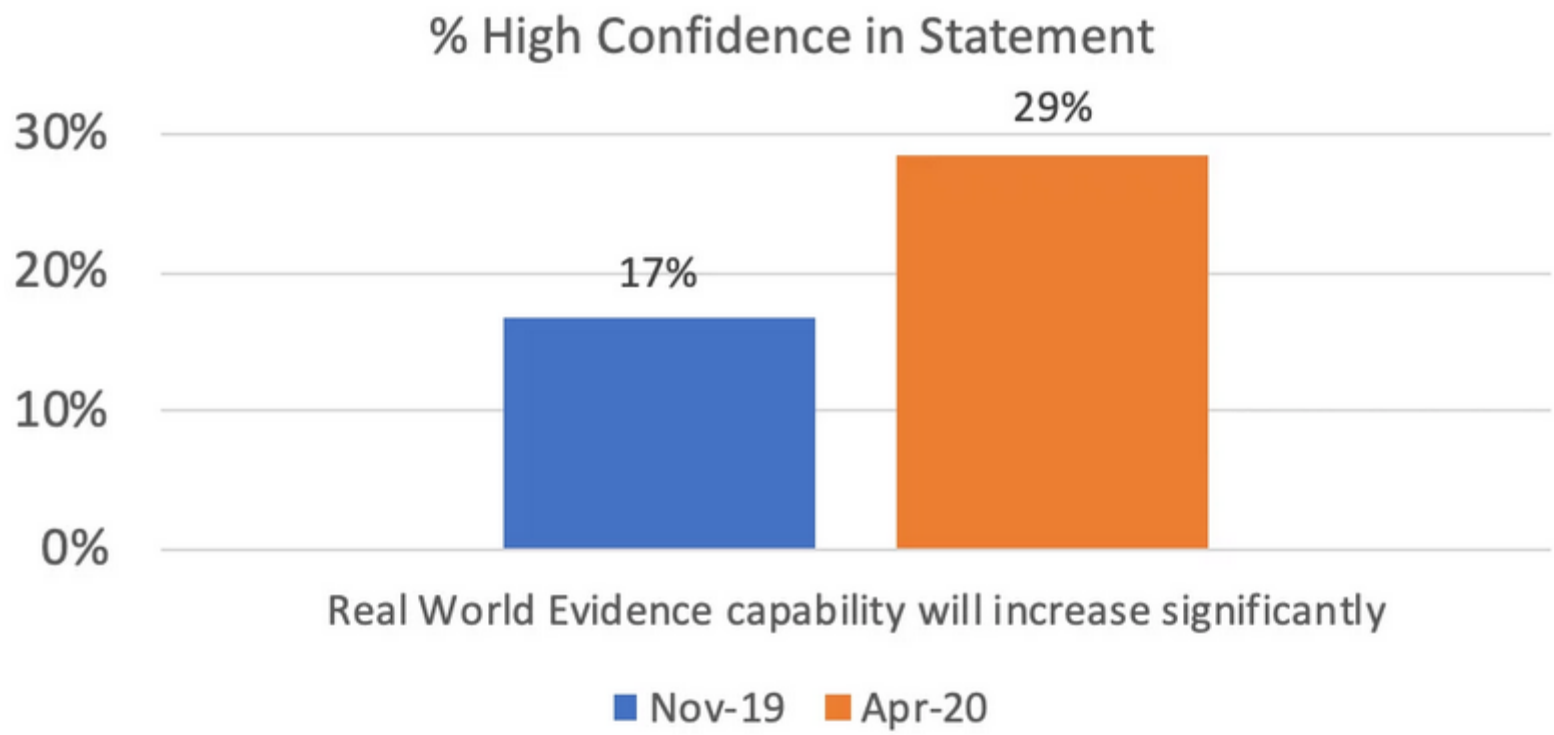

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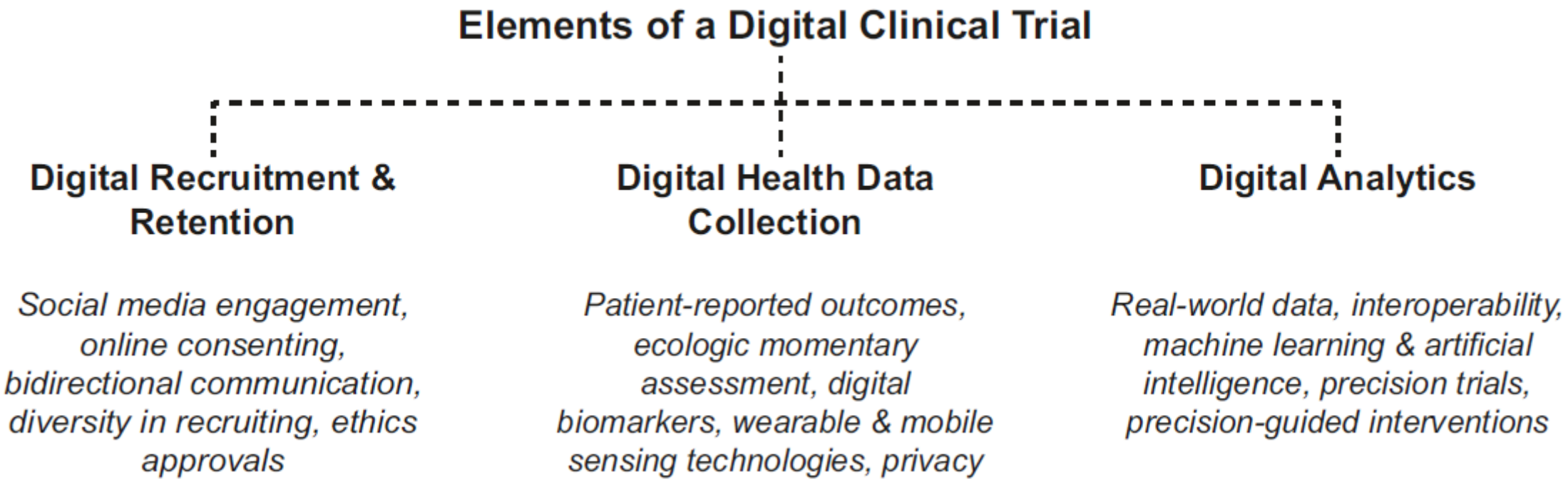
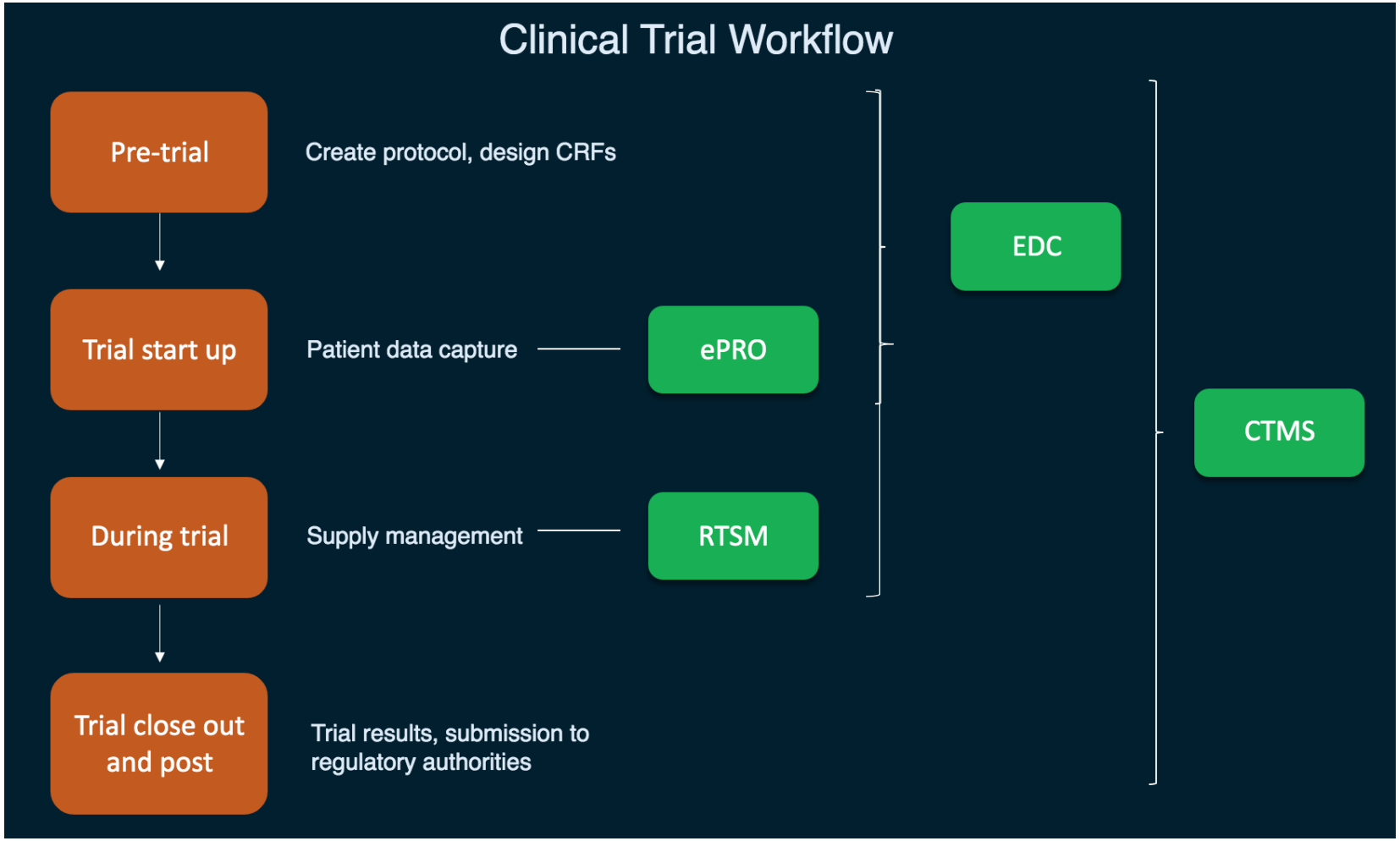


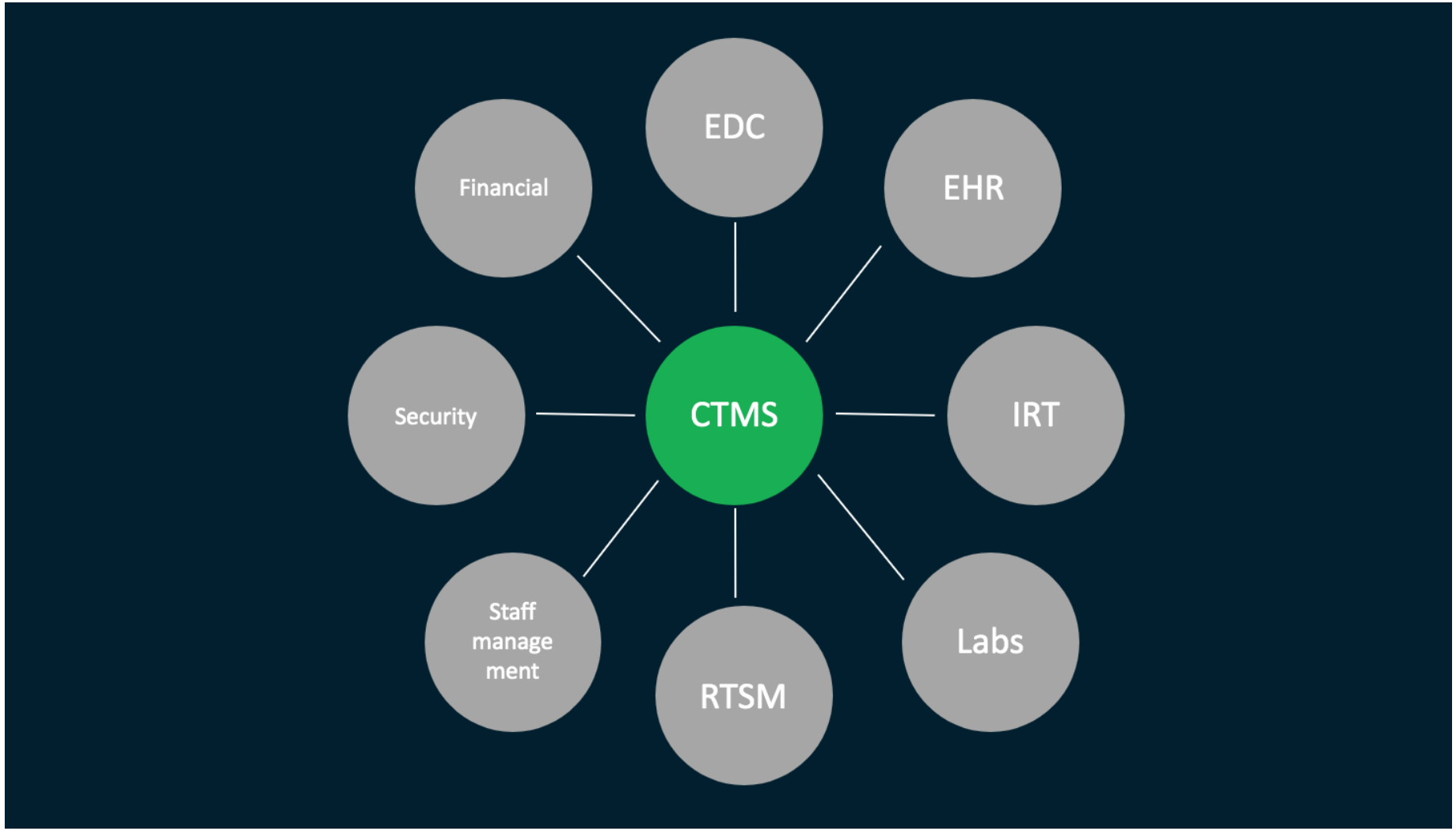
Source: Digitizing clinical trials

Simplified visualization of main clinical trial systems and their functions



Source: Clinical Trial Software: Understanding EDC, CTMS, ePRO, RTSM, and Addressing Industry Challenges

CTMS integrations



Software-Enabled Clinical Trials

Many companies offer products that span across categories. To keep the map simple, the logo is in the "primary" product.
Have an update? Share via www.ElektraLabs.org/decentralized-trials

Software-Enabled Clinical Trials

Conduct Study

Design Protocol
ProofPilot, trials.ai, HealthVibe, AllTrials

Enabling Non-Profits & Consortia [0]
Clinical Trials Transformation Initiative, CDISC, imi, TransCelerate, Critical Path Institute, Digital Therapeutics Alliance, DIA

Start-Up Study [1]
CenterWatch, IQVIA, Veeva, WIRB, medidata, COVANCE, goBalto, ERT, TriNetX, trifecta, teckro, FIRECREST

Recruit Patients
Mendel.ai, Driver, Trialx, antidote, Clara, QuintilesIMS, trialbee, mprove, DEEP 6, SubjectWell, ClinicalConnection, patientslikeme, myHealthTeams, VITALTRAX, STUDYKIK, langland, seeker, Be the Partner, Trialspark, FindMeCure, myTomorrows

Manage Operations [2]
PAREXEL, BIOCLINICA, MyTrials, SIGNALPATH, Veeva, ORACLE, SIEBEL, medidata, Longboat, thoughtsphere, COVANCE, Florence, REALTIME, Trialspark, clinical research.io, SimpleTrials, Welkin, Cognizant, veeva, comprehend, salesforce, health cloud, FORTE, CluePoints, greenphire, ClinPay

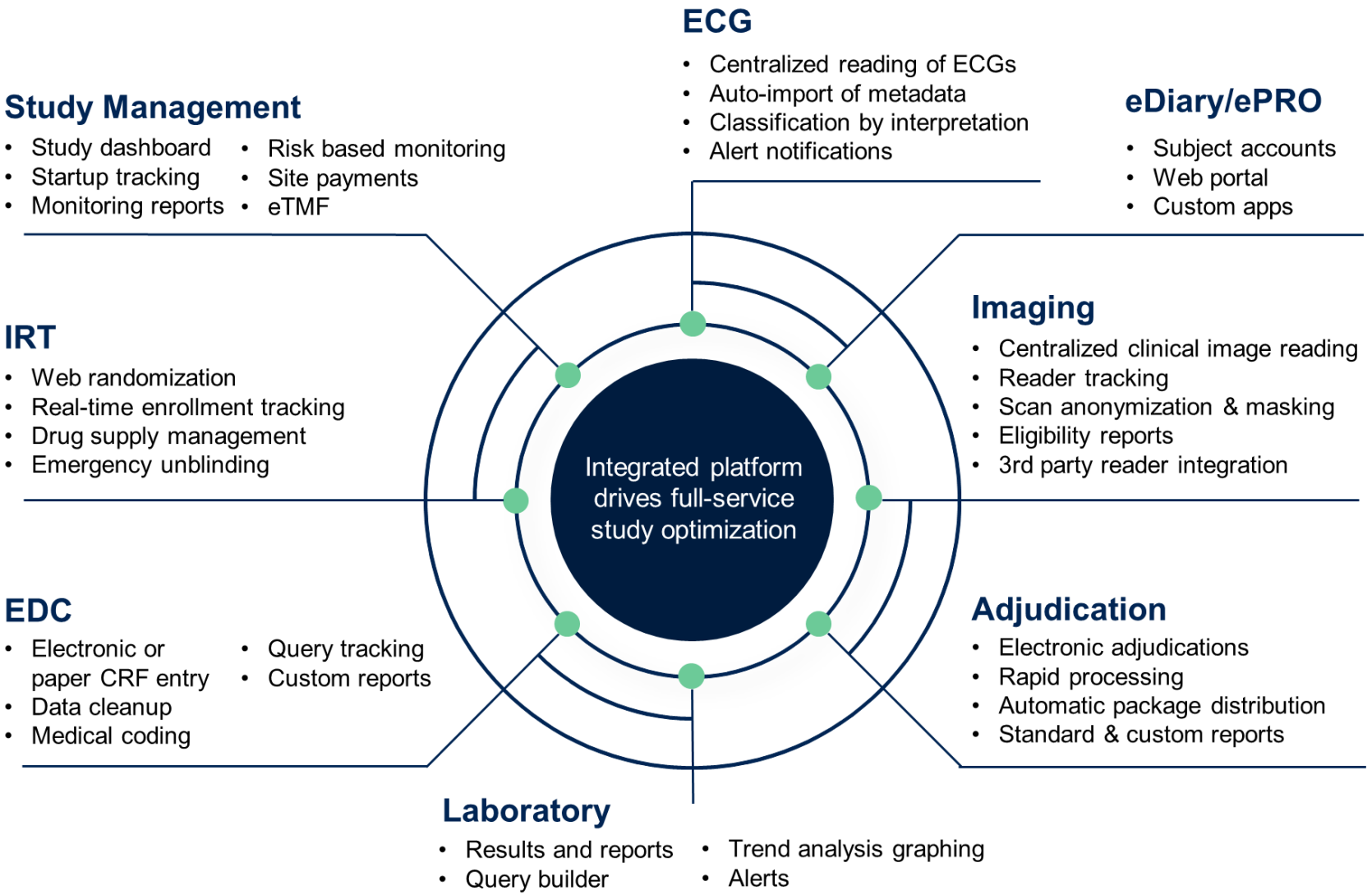
Drug & Supply Logistics
Slope.io, mesm, 4G, endpoint, CENDUIT, Bracket

Collect and Analyze Patient-Level Data

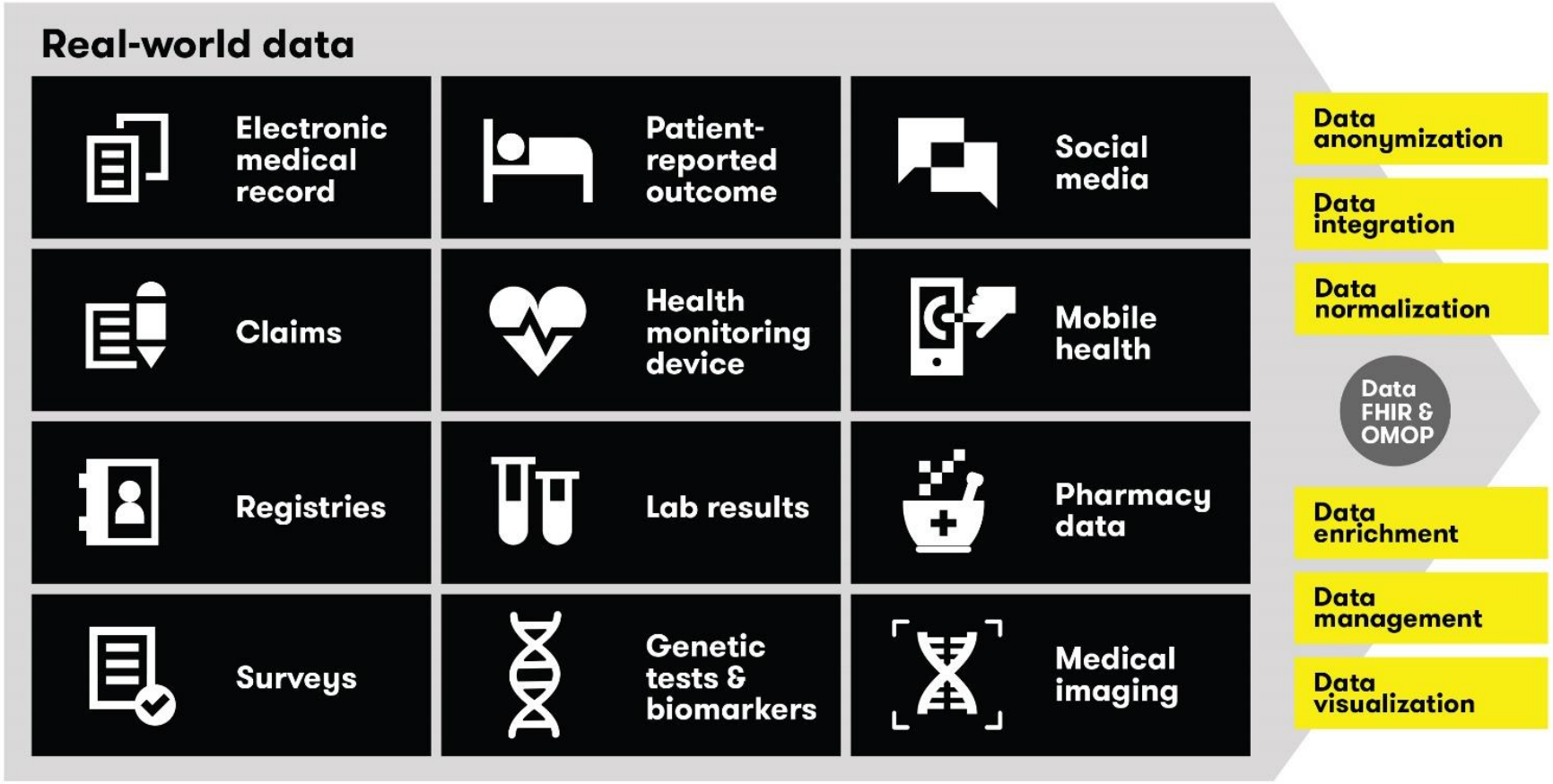
Patient Data Management (e.g., EDC, eCOA, Digital Biomarkers) [3]
Veeva, REDCap, medidata, Human API, ClinPlus, OpenClinica, COVANCE, VALIDIC, fitabase, IBM Watson Health, eClinical, ORACLE, QuintilesIMS, evidation, medrio, Biospective, ERT, trialbee, Bracket, ActiGraph, trials.ai, mprove, 2net, ResearchKit, Clinical Studio, phys iQ, ALMAC, koneksa, yprime, EmpiraMed, xclinical, FORTE, verily, umotif, Viedoc, AliveCor, CRF HEALTH, MedNet, Altavoz, snapIoT, PHILIPS, tonic, assisTek, AiCure, vivifyhealth

Decentralized Trials
Sage, Science 37, CLINPAL, koneksa, IQVIA, Trialx, monARC, Data1, EmpiraMed, evidation, MEDABLE, medidata, THREAD, snapIoT, VIRTRIAL, aparito

Integration problem



From RWD to RWE



RWE served on a platform

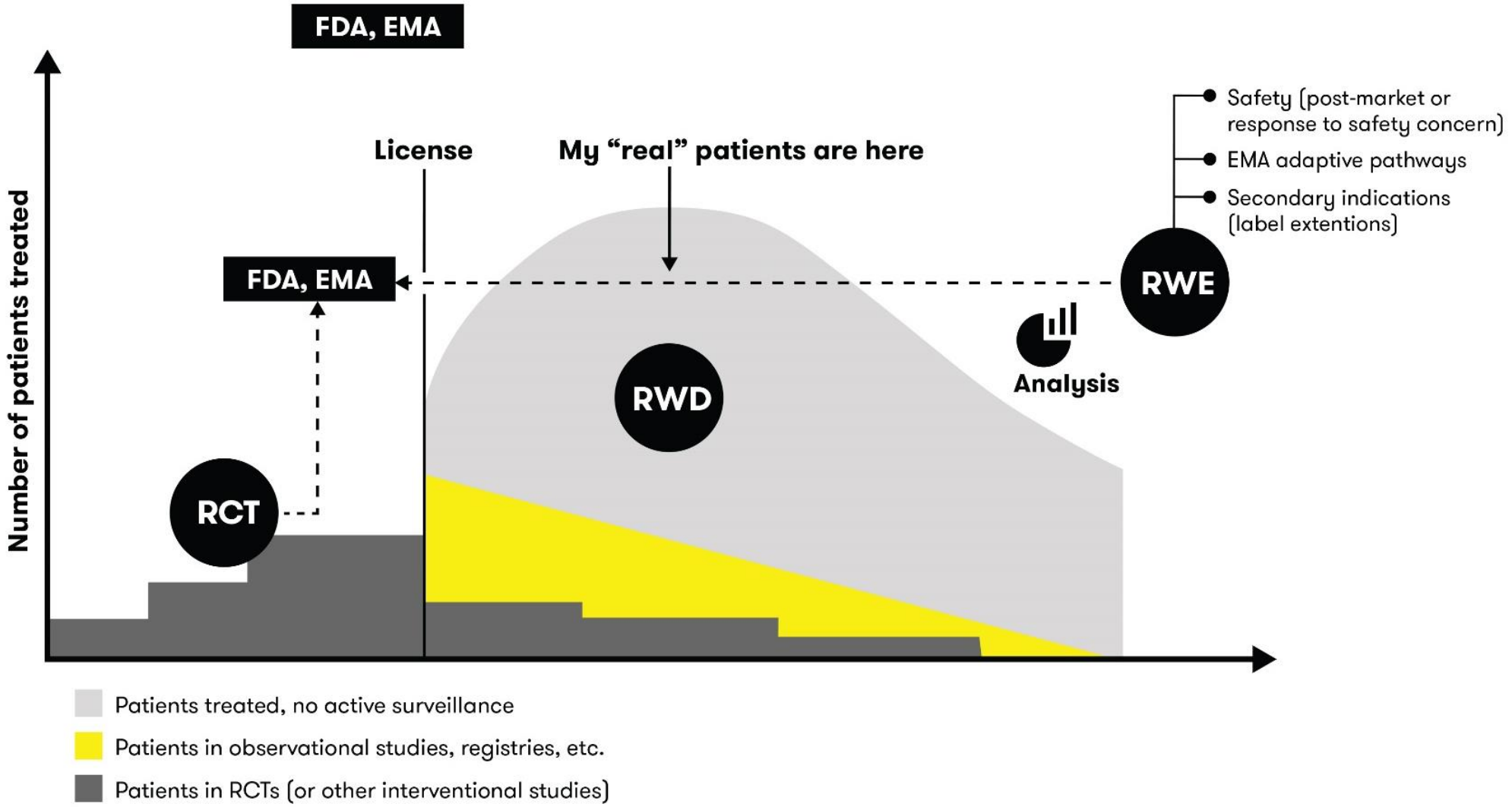
Platform with standardized data accelerates the healthcare data flow by using standard common data models (FHIR, OMOP).

The platform is data agnostic and can ingest, standardize and leverage data to provide actionable evidence and insights.

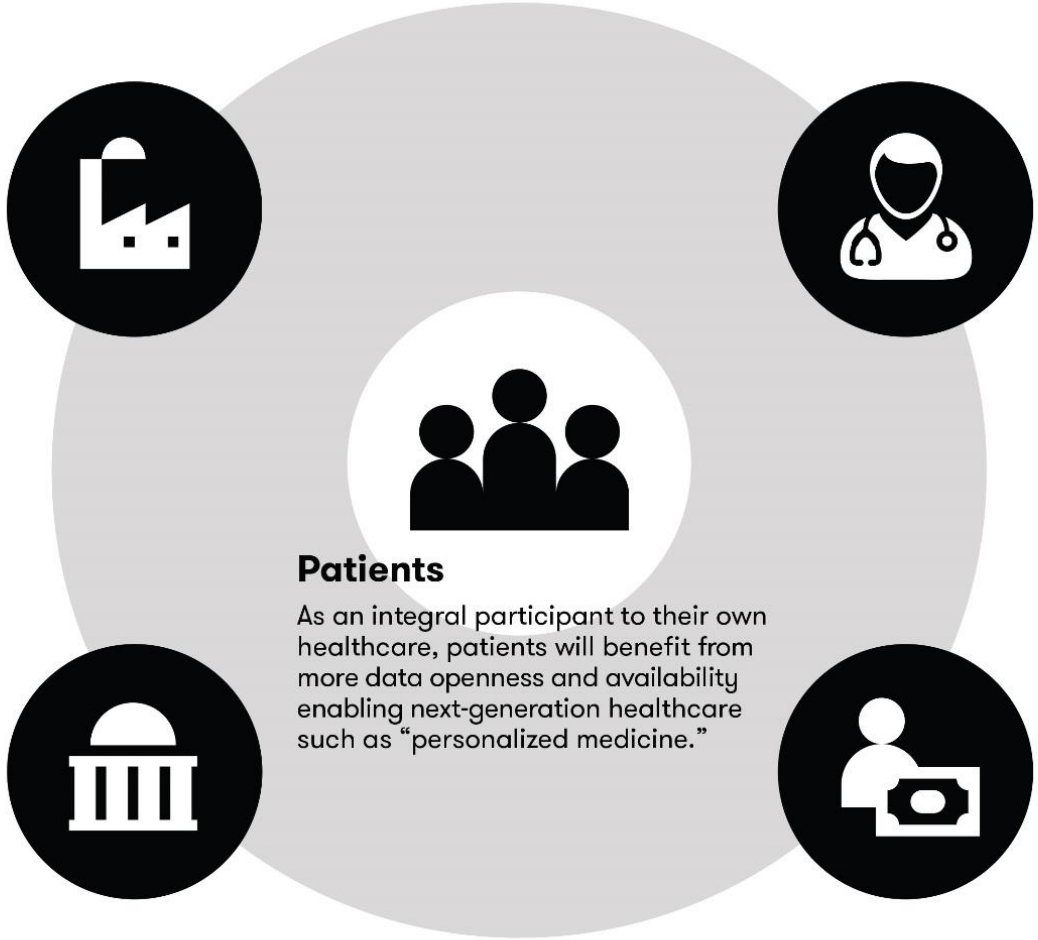
The evidence generated from the curation of real-world data is used at all stages of the drug or medical device lifecycle.

Source: How real-world evidence transforms the entire healthcare ecosystem

The contrast between randomized clinical trial (RCT) and RWD



Who is using RWE?



Manufacturers

From identifying unmet needs to clinical trials optimization to market access and pharmacovigilance, the industry actors are high "consumers" of RWE.

Healthcare providers

They gain the ability to "augment" their intelligence on patient profiles, diagnosis, treatment pathway and potential adverse events. They are able to leverage more efficient clinical decisions through evidence-based methodologies and systems.

Patients

As an integral participant to their own healthcare, patients will benefit from more data openness and availability enabling next-generation healthcare such as "personalized medicine."

Regulators

FDA and EMA use the data traditionally for post-market safety and benefit/risk studies. FDA with the 21st Care Act clearly puts RWE as a key enabler for regulatory decisions and market approvals.

Payers

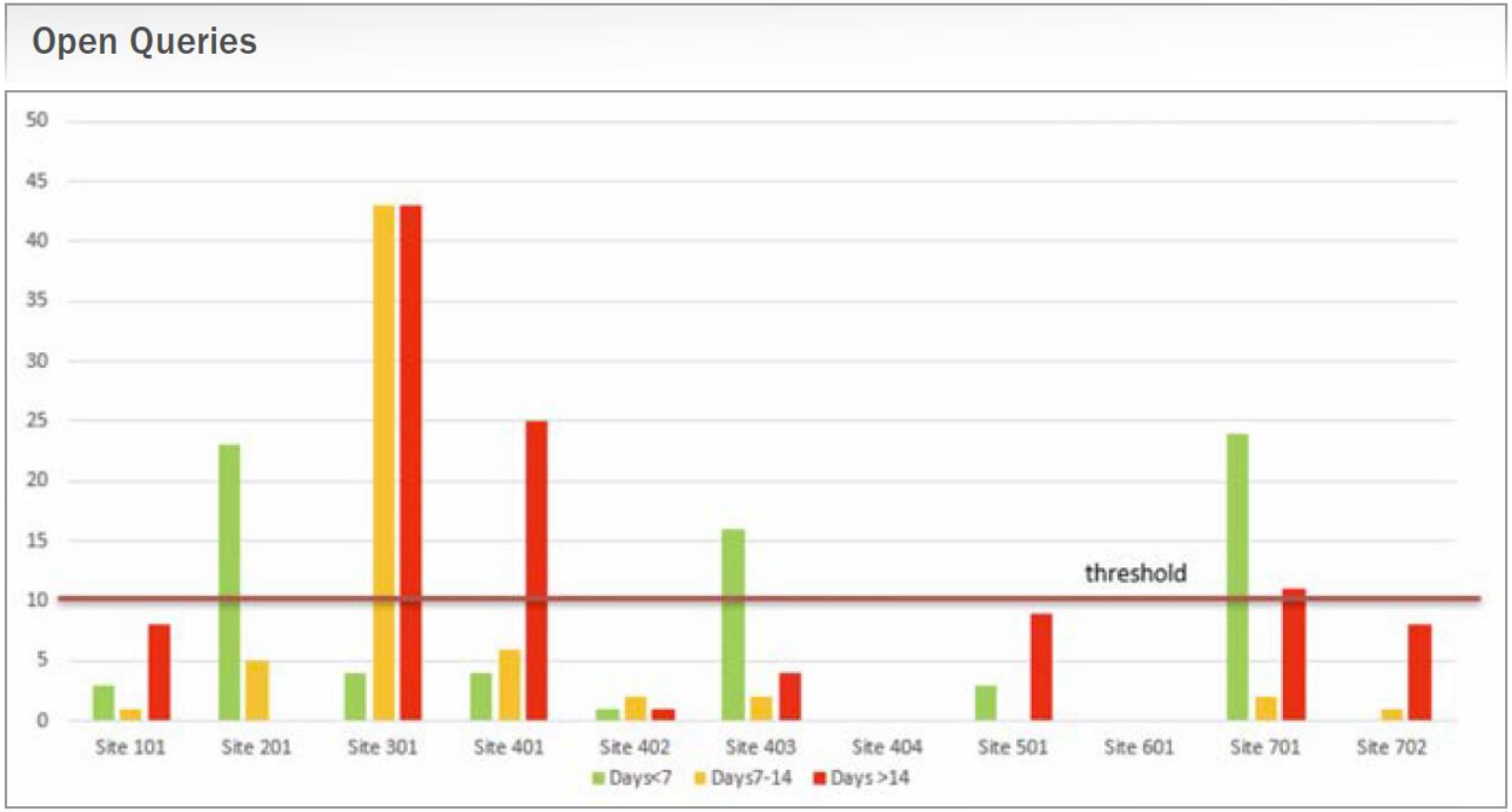
They can manage cost of care and good usage. RWE also enables insights and decisions for personalized reimbursement models based on usage, value and outcome.

Source: How real-world evidence transforms the entire healthcare ecosystem

Risk-Based Monitoring

RBM is developing, but there are no generally accepted standards

Risk-Based Monitoring Example



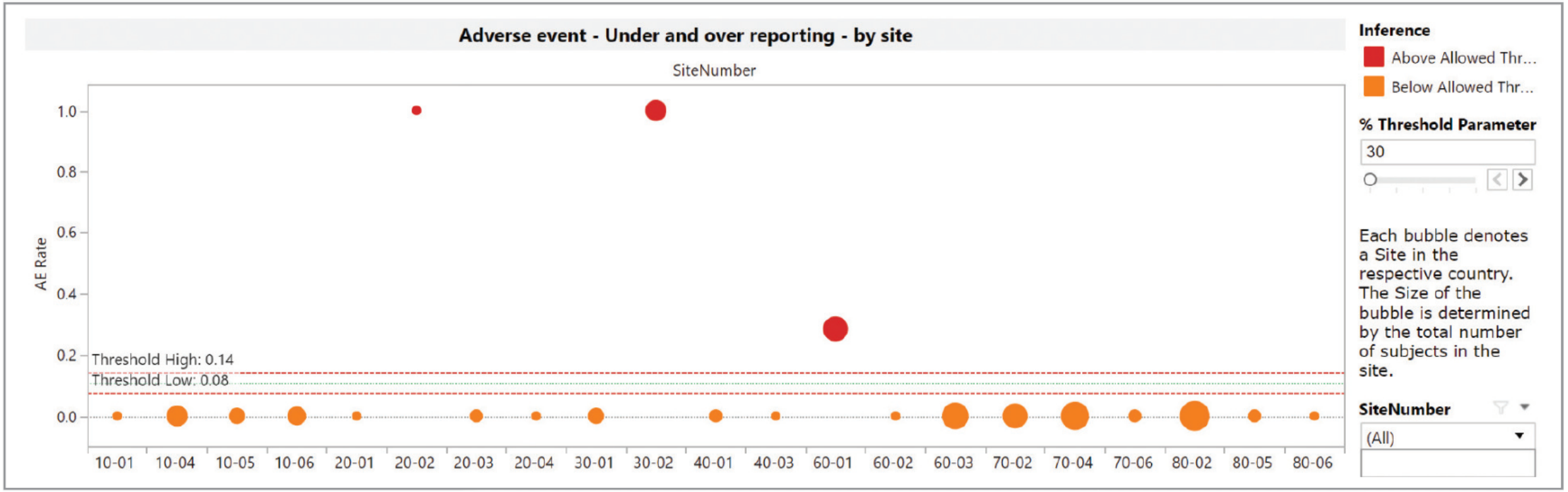
Source: Arid

Figure 1. An example of key risk indicator duration of open queries.

Source: Central RBM Supports Reduced Cost, Higher Data Quality

Risk-Based Monitoring Example

Adverse Event Rate



Source: Abraham

Figure 4. Adverse event reporting data by site.

Source: Weighing the Benefits of RBM Implementation

Blockchain, Artificial Intelligence (AI), Mobile/Connected Devices

Promising technologies

Source: Deloitte: Reimagining digital clinical trials

Blockchain, Artificial Intelligence (AI), Mobile/Connected Devices

Reimagination opportunity	Key process area	Required ecosystem	Enabling technology
Medication delivery for remote trials	**Clinical supply chain** The process of ordering, tracking, and delivering medication can be enhanced to deliver medication to a patient during a remote/ virtual trial.	**Manufacturer, distributors, & clinical sites** Coordination across the entire supply chain ecosystem will be needed to ensure that the right medication reaches the right patient at the right time.	**Blockchain** This technology can enable various supply chain entities to effectively share information through a distributed network to create end-to-end visibility that will reduce product waste and improve overall clinical trial efficiency.
Real-time reviews	**Patient monitoring** The process of surveying a patient's sentiment and well-being can be altered to include real-time feedback throughout the clinical trial journey.	**Sponsor, clinical site, investigators, HCPs** These stakeholders will need to outline the key milestones that will create patient feedback opportunities and ensure that action is taken to address criticisms.	**Artificial intelligence** AI-enabled assistance (e.g., Alexa or chatbots) could be leveraged to ask patients to rate their experiences and solicit specific information through a guided conversation.

Source: Deloitte: Reimagining digital clinical trials

Blockchain, Artificial Intelligence (AI), Mobile/Connected Devices

Data synchronization

Study design

A new process can be added to the study design to account for the data types that will be shared during and after a trial. This includes identifying those data elements to which the patient must be blinded during the study and those which are unblinded.

Sponsor, clinical site, investigators, HCPs

These stakeholders will need to work together to coordinate tracking and analysis of patient data that ultimately will be shared.

Mobile/connected devices

Connected devices could serve as one of many potential end points where patient data could be stored.

Data marketplace

Post-trial data return

A new process can be established to intake data from patients participating in a marketplace, be it through their donating data or companies purchasing data from them.

Multiple sponsors and other clinical research institutions

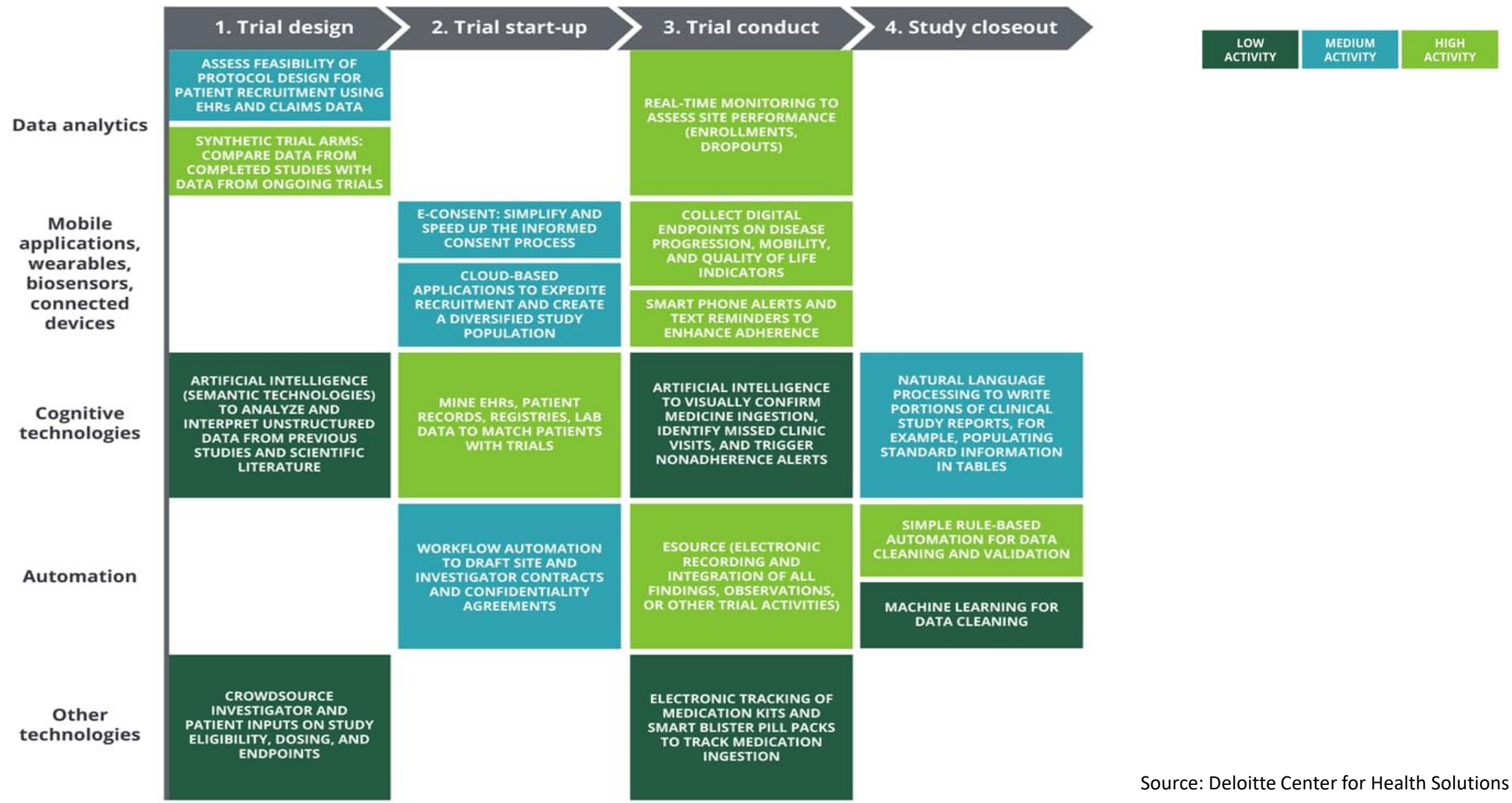
An industry-wide marketplace will need to be established where patients from different clinical trials can co-locate to make their data available.

Blockchain, AI

Blockchain can be used to establish a decentralized marketplace network where no sponsor has an outsized role and where patient identities are shielded until a transaction agreement is completed. AI can be used to analyze data sets (non-patient identifiable) to determine which ones match a sponsor's needs.

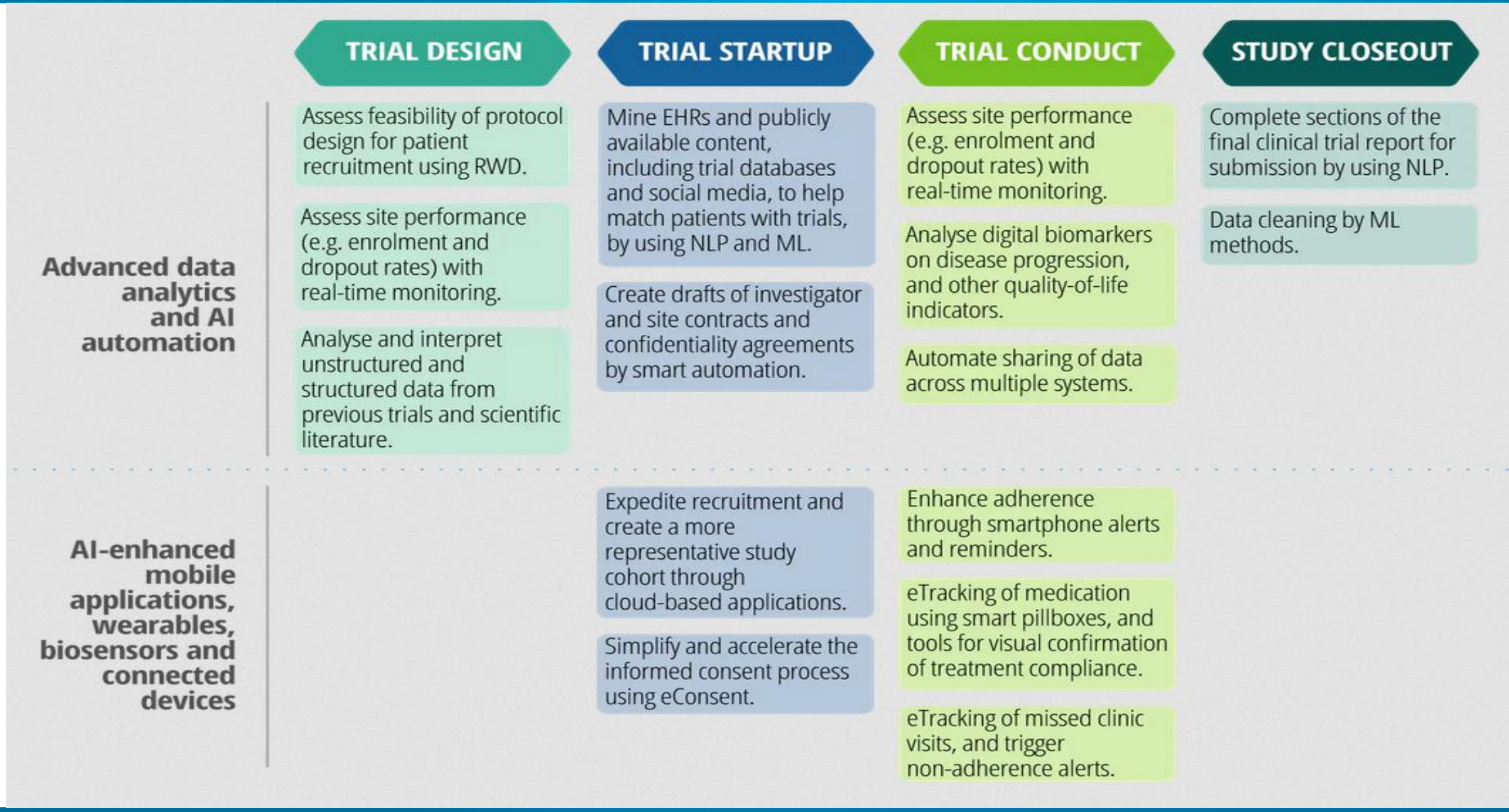
Source: Deloitte: Reimagining digital clinical trials

Market activity around digital innovation in clinical development



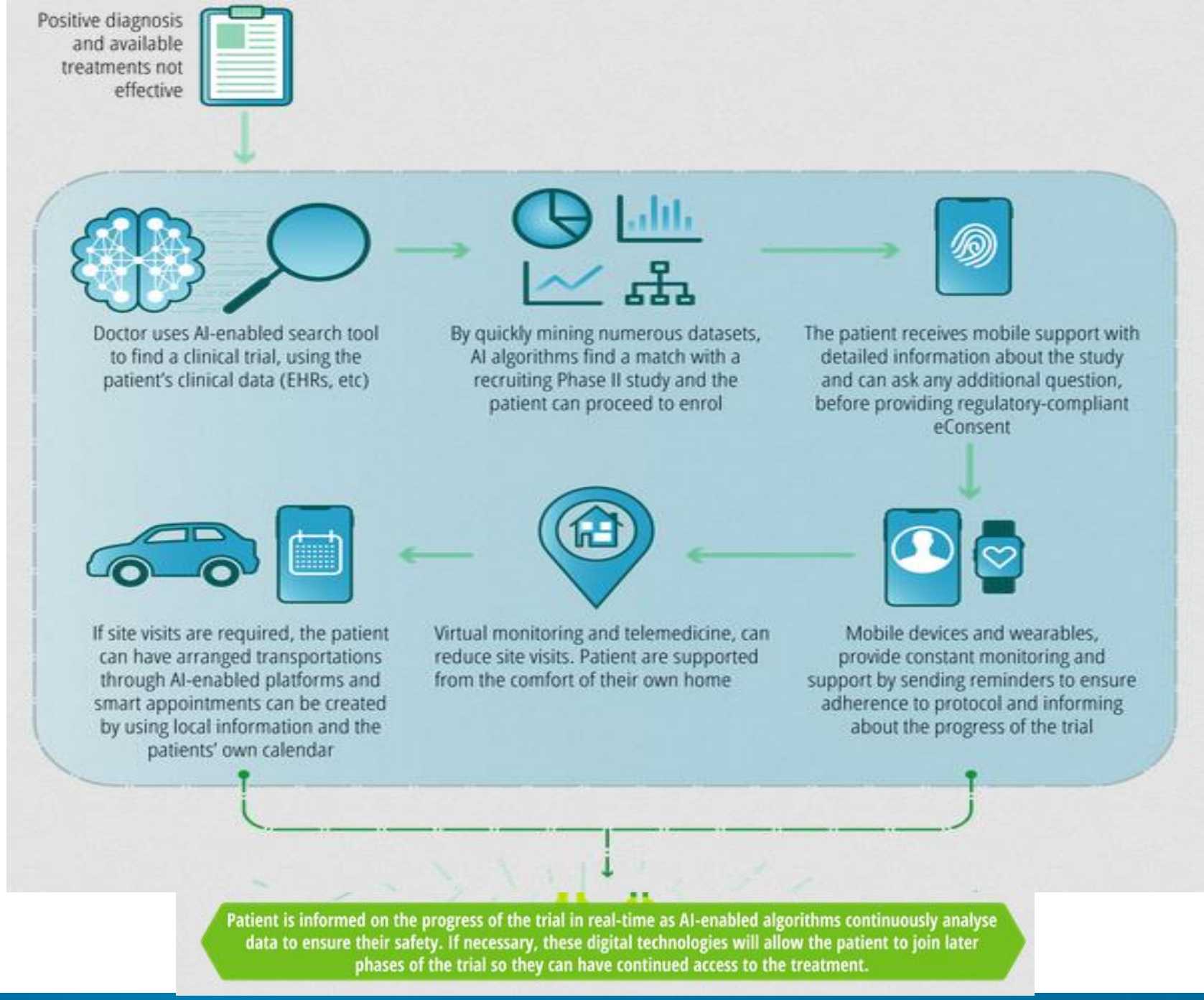
Source: Deloitte Center for Health Solutions analysis

Applications of AI-enabled technology in clinical trials



Source: Intelligent clinical trials

Patient’s journey through an AI-enabled clinical trial



Source: Intelligent clinical trials

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