Tech Innovation & Data Empowerment

YaFang Wu, Vice President, Data Management (global)
Parexel International

Tim Chen, Director, Customer Strategy
Medidata Solutions, a Dassault Systèmes Company

Aritra Bhowmik, APAC Site Success Manager
Cognizant

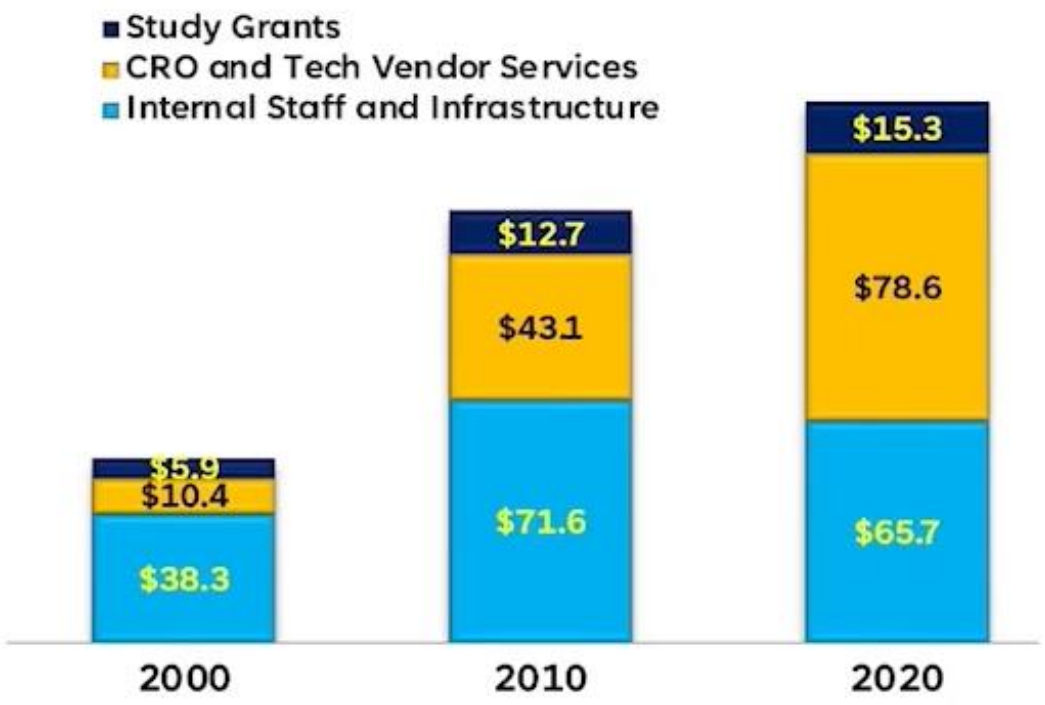
SCRS
Society for Clinical Research Sites

How have things evolved

Protocol Design Practice

Phase III Pivotal Trials *(Means)*	2010	2020	10-Year Change
Total Endpoints	13	22	69.2%
Total Eligibility Criteria	34	30	-11.8%
Total Procedures	187	263	40.6%
Total Countries	9	15	66.7%
Total Investigative Sites	65	104	60.1%
Procedures per Visit	11	13	18.2%
Total Patients Randomized	597	632	5.9%
Total Data Points Collected	929,203	3,560,201	283.2%

Global R&D Spending Segments

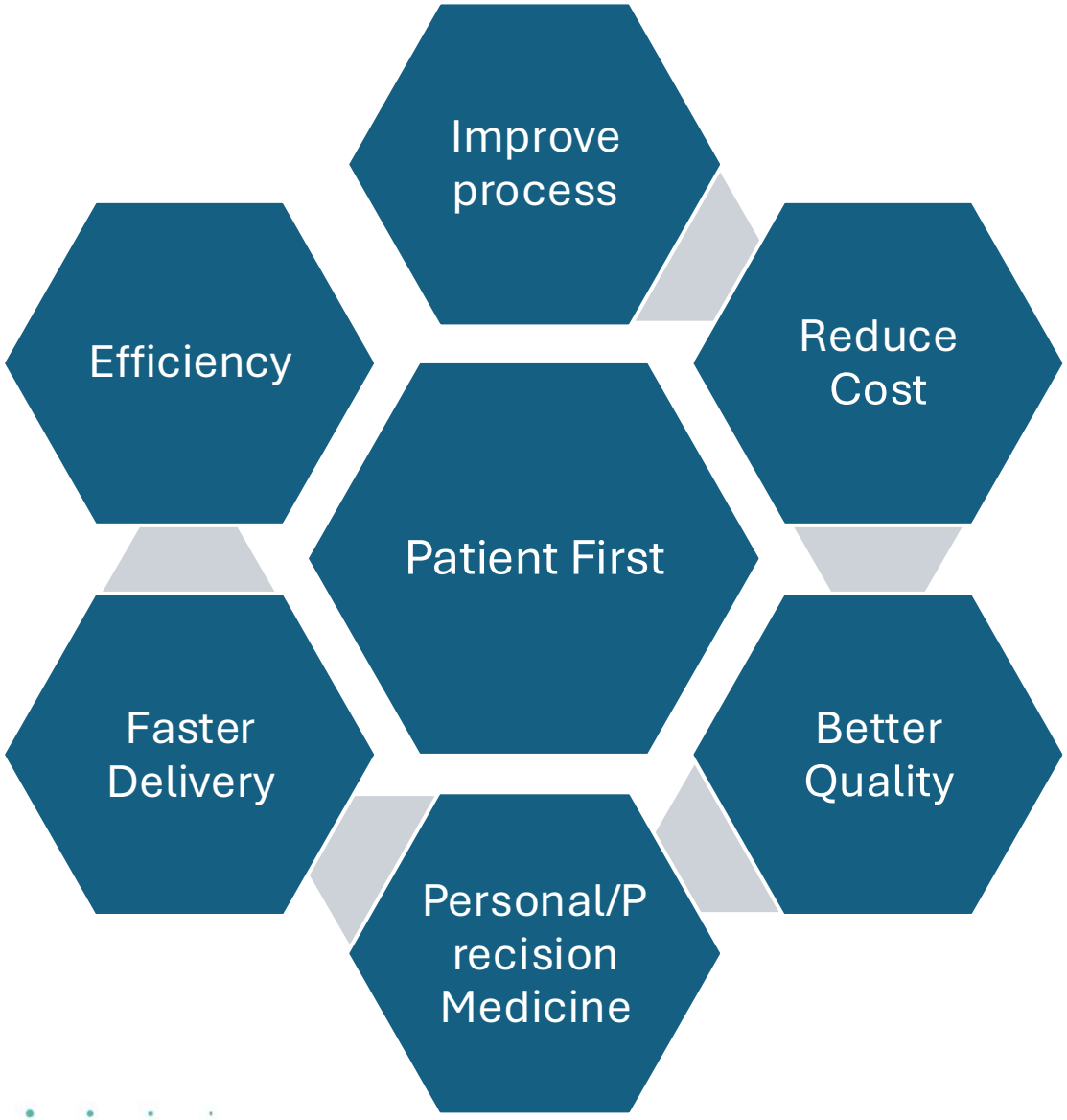


Technology and AI are key to the future of Drug Development

FDA Definition of Digital Health Categories:

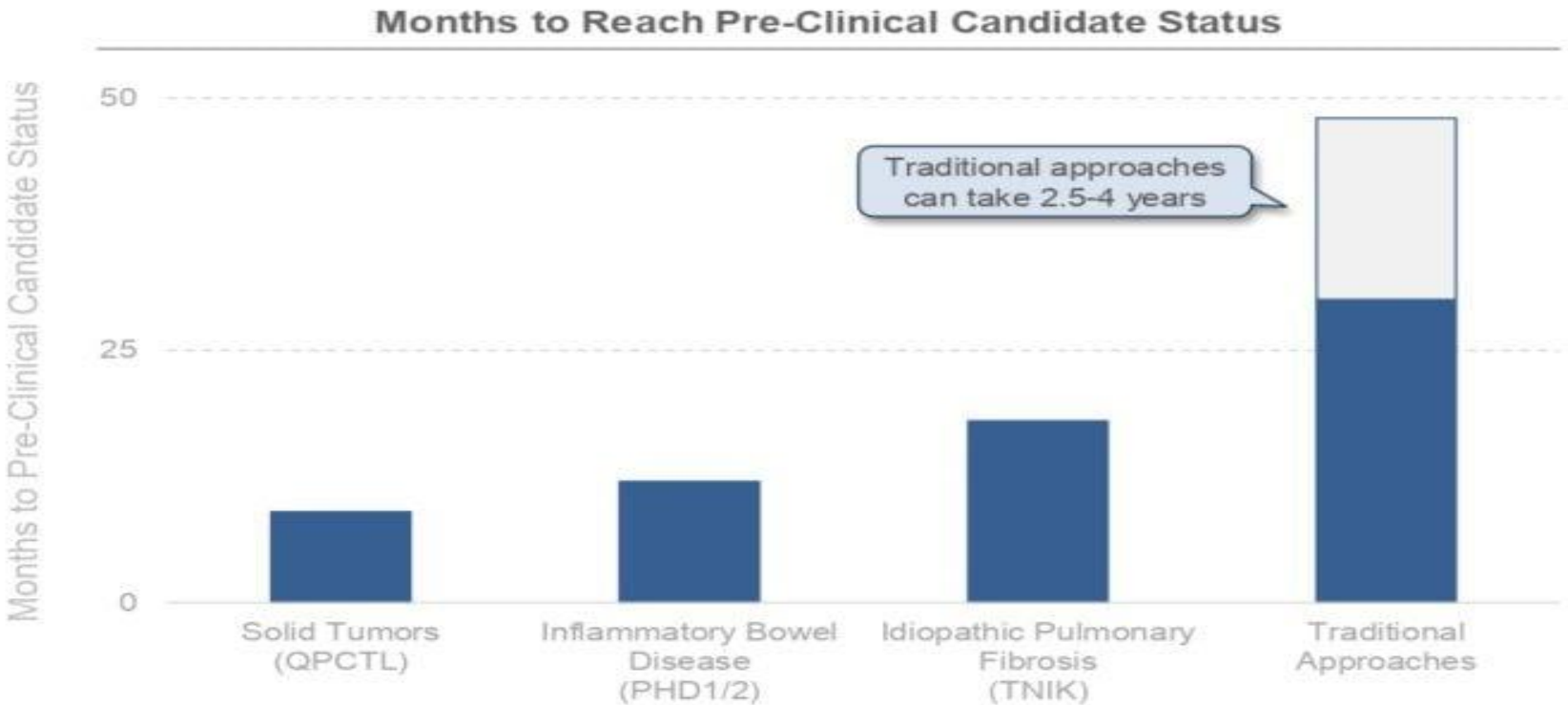
- Mobile health (mHealth)
- Health information technology (IT)
- Wearable Devices,
- Telehealth and telemedicine
- Personalized medicine

What Are the Benefits of Digital Health Technologies?



Research =
30%-80% Reduction in Medical R&D Timelines, per Insilico Medicine & Cradle

AI-Driven Drug Discovery – 2021-2024, Per Insilico Medicine, Cradle & BioPharmaTrend



Cradle

Pharma companies that use Cradle are seeing a 1.5x to 12x speedup in pre-clinical research and development by using our GenAI platform to engineer biologics.

- Stef van Grieken, Co-Founder & CEO of Cradle, 5/25

Note: Pre-Clinical Candidate Status marks the point at which a lead molecule (or biologic) has satisfied all discovery-stage gates and is officially handed off to the development organization for work related to beginning human clinical trials. Figures collected from 2021-2024. Source: Cradle, Insilico Medicine via BioPharmaTrend, 'Insilico Medicine Reports Benchmarks for its AI-Designed Therapeutics' (2/25)

Regulatory Acceptability

Guidance likely to raise more questions than answers for LLMs

- Drug development is highly regulated
- Clinical Trial Sponsors are cautious of regulatory risk
- EMA Draft Reflection Paper indicates alignment to a 'risk-based approach'
  - Risk to patient
  - Risk of error in regulatory decision-making
- Concerns with lack of transparency, potential for bias and error, negative or harmful impacts in use
- EU AI Act & GDPR legislation both apply
  - Potential to encourage shift towards open-source LLMs?

Per EMA: *"… the use of exceptionally great numbers of trainable parameters arranged in non-transparent model architectures introduces new risks that need to be mitigated both during model development and deployment to ensure the safety of patients and integrity of clinical study results. Also, as the overarching approach is inherently data-driven, active measures must be taken to avoid the integration of bias into AI/ML applications and promote AI trustworthiness ."*

Per FDA: *"There are also concerns with using algorithms that have a degree of opacity, or algorithms that may have internal operations that are not visible to users or other interested parties. This can lead to amplification of errors or preexisting biases in the data. We aim to prevent and remedy discrimination — including algorithmic discrimination, which occurs when automated systems favor one category of people over other(s) — to advance equity when using AI/ML techniques."*

LLMs in clinical development
Where can we operate safely?

- Productivity / efficiency
  - e.g., where business have large numbers of staff carrying out repeatable tasks
    - Statistical Programming
    - Data Management & Monitoring
    - Medical Writing
    - Safety & PV
    - Patient Recruitment
- Decision-support
  - e.g., rapid synthesis of curated data enabling sponsor decision-making
  - Risk is borne by sponsor

- **'Fixed function' applications simpler to validate and therefore simpler to ensure traceability, auditability**
  - Model released does not self-learn in use
  - Looks more similar to existing technology stack

- **'Growth function'** apps that continue to learn-in-use from input data sources are attractive in some settings, but present additional complexities
  - What does system validation look like?

Conclusions – Caution for Speed

- We are at the beginning of an important journey
- Undoubted benefits will drive rapid adoption of LLM-based AI apps in Clinical Development
- Approach will be informed by a concern for known risks as well as emerging evidence on regulatory acceptability

- For simple fixed function Apps there is strong basis for confidence when:
  - Used in contexts with already strong QC
  - Prompts carefully engineered, managed in-App
  - Model fine-tuned as needed
  - Well-constructed user training
  - Pre-defined performance monitoring plan

- Further evidence on the efficacy of human oversight is needed

Timothy Chen
Director, Customer Strategy
Medidata Solutions, a Dassault Systèmes Company

SCRS
Society for Clinical Research Sites

Where are we today with AI and drug development?

- AI is still hot, with promising technology breakthroughs being announced almost daily
- Many pilots failed to yield expected Return on Investment
- “AI fatigue” – what are the reasons?
- Same challenges exist – how can we view them differently?
  - Smarter, data-driven, continuously optimized trials
  - Siloed, functional execution > multi-functional, orchestrated execution
  - Periodic review > continuous monitoring and optimization
  - Reactive execution > proactive, predictive, autonomous execution

How can AI address these challenges?

Looking at today's challenges in Clinical Operations

Pain Point	Operational Impact
Software and Data Silos	Trial teams often use 10+ disparate point solutions (e.g., EDC, CTMS, eTMF, RTSM, eCOA). Manually transferring and reconciling data across systems increase the risk of additional time and human error.
Recruitment and Diversity Delays	Over 80% of clinical trials miss enrollment timelines. Finding eligible patients and ensuring trial cohorts reflect diverse demographic populations remains a major hurdle.
Mid-Study Protocol Amendments	When a trial protocol changes mid-study, updating legacy systems often requires study pauses, costly re-configurations, and manual data fixes.
Inefficient Data Cleaning & Database Lock	Relying on 100% manual Source Data Verification (SDV) creates massive data backlogs, delaying database lock and regulatory submissions.
Site Administrative Burden	Complex systems and slow site payments frustrate clinical sites, leading to site fatigue and high turnover rates.

Comparing Point Solutions to Unified Platforms

- Point solutions have offered solutions for specific problems

- However, they are hard to scale in two ways:
  - **System architecture:** Practically, disparate point solutions require manual integration and have built-in workflow complexity and end user burden
  - Unified platforms can integrate the work of multiple solutions and help scale them to an enterprise level
  - **Data architecture:** disparate point solutions will have different file formats, data structures, and nomenclature that complicate consolidate and analysis – this directly impacts the effectiveness of AI tools

- Unified platforms offer a consistent system and data foundation, which can scale up to enterprise-level requirements for drug development

Looking at today's challenges in Clinical Operations

Pain Point	Platform Approach
Software and Data Silos	Unified platform with a single source of truth and data architecture.
Recruitment and Diversity Delays	Using historical data from tens of thousands of past trials, AI models can predict which trial sites are most likely to hit enrollment targets and meet diversity benchmarks.
Mid-Study Protocol Amendments	Modern system architectures allow study teams to push protocol amendments and mid-study design changes live without taking the system offline.
Inefficient Data Cleaning & Database Lock	AI and analytics monitor data remotely, with automated systems flagging data anomalies, protocol deviations, or potential fraud in near-real-time, providing teams to target high-risk areas proactively.
Site Administrative Burden	Single login, consistent user look-and-feel across the site and patient experiences

Applications in the Asia-Pacific Region

- Cloud Infrastructure for Data Sovereignty
- Mitigating "Drug Loss" via Data & Analytics
- Unified Localization for eCOA & Patient Data
- Randomization and Trial Supply Management (RTSM)

AI & Advanced Analytics in Clinical Trial Operations

ARITRA BHOWMIK – APAC Site Success Manager,

Cognizant

How real-time data capture and automated quality checks are accelerating drug development — with a regional lens on Asia

SCRS
Society for Clinical Research Sites

Why This Matters Right Now

FDA launched its first real-time clinical trial pilot in April 2026 — regulators are now betting on this shift too

2

Live FDA proof-of-concept trials

AstraZeneca (lymphoma) & Amgen (lung cancer) streaming AI/cloud data feeds directly to FDA

20–40%

Projected cut in trial duration

FDA officials' estimate from the real-time monitoring pilot

$120M

Projected annual savings

Enough to fund up to 3,000 rehired FDA scientists, per agency estimate

"For 60 years, we've conducted clinical trials the same way, where key data signals can take years to reach the FDA... We are boldly advancing a modern approach."

— FDA Commissioner Marty Makary, April 2026

Four Operational Pillars

How AI and analytics are changing day-to-day trial operations

01

Real-Time Data Capture

EDC gives way to continuous feeds from EHRs, wearables & labs — cutting double entry and site-to-monitor lag.

APAC data-capture market: ~21.84% CAGR through 2035 — fastest of any region.

02

Automated Quality Checks

Risk-based monitoring flags anomalies and deviations live, instead of surfacing them in queries weeks later.

FDA's Jan 2025 draft guidance: sponsors must now demonstrate, not just claim, AI/ML fitness for purpose.

03

Efficiency & Reduced Workload

Pattern recognition and continuous learning — not just faster digitization — reshape eligibility review and site selection.

ICON's AI site-selection tool: +26% recruitment, +24% hitting first-patient-in targets.

04

Adaptive, Data-Driven Trials

Live visibility can compress the phase-to-phase hiatus, enabling more continuous, adaptive trial designs.

Digital twins (EMA-qualified since 2022): 10–30% sample-size cut, power preserved.

Some Proof Points:
Real AI Impact aligned with the operational pillars

01

Real-Time Data Capture

Clario's AI reads continuous ECG & spirometry streams, flagging poor recordings on the spot — not weeks later.

02

Automated Quality Checks

Saama's AI cuts query-generation time from 30 to 3 minutes; Medidata's Targeted SDV took one sponsor from 100% to 15–20% SDV.

03

Efficiency & Reduced Workload

Tempus/Deep 6 AI screens out ~72% of ineligible patients automatically, matching candidates up to 10x faster than manual review.

04

Adaptive, Data-Driven Trials

Unlearn.ai's EMA-qualified (since 2022) digital twins cut sample size 10–30% in published neuro/cardio trials; Insilico Medicine (China/HK) cut candidate timelines to ~1 year, from ~4.5.

Cognizant's Point of View on AI

Most of the industry still treats AI as a cost lever — we're building for a different outcome

> *"AI's biggest win in trial operations isn't fewer FTEs — it's faster, more adaptive trials that reach patients sooner. Cost reduction should be the by-product, not the goal."*

— Cognizant Life Sciences, point of view

Automate the mundane

Daily workflows are being automated and orchestrated via agentic AI with human in the lead

Assist with the complex

Enable and empower site staff with intelligent customized agents. No more dedicated time allocation for learning new systems.

Escalate the consequential

Proactive monitoring, flagging around what can go wrong to the human in the lead

State of adoption, right now: 72.9% of early adopters already report shorter trial timelines — but only 11% of firms have AI fully implemented across trial operations.

Medidata/Everest Group 2026 State of AI in Clinical Trials report; WCG CenterWatch 2025 AI Benchmarking Report

Cognizant's Readiness Framework

What we tell sponsors and sites to get right before scaling AI in trial ops

01

Talent & Change Management

Reskill coordinators and CRAs so AI augments judgment instead of cutting headcount — aim for higher-value work, not smaller teams.

02

Technology Investment

Treat automating admin work as table stakes, then re-evaluate whether legacy platforms can support what's next.

03

Modernized Data Management

Closed, proprietary legacy systems can't feed AI what it needs — fix the data plumbing first; the model is the easy part.

04

Transparency

Clear, consistent communication about how AI is used builds the trust that real adoption depends on.

The Asia Regulatory Landscape

Regulators are building AI into their own review processes — not just asking sponsors and sites for cleaner data

CN

China — NMPA

- National "AI + Drug Regulation" roadmap published Apr 2026, milestones to 2030/2035
- Goal: dynamic, risk-based supervision using onsite + non-onsite oversight
- Eligible innovative-drug INDs reviewed in 30 working days

IN

India — CDSCO

- CDSCO x IndiaAI hackathon (Apr 2026) automating document review & SAE triage
- End-to-end digital regulatory platform launching within 18 months
- 25–30% of eligible innovative products under review for trial waivers

TW

Taiwan — TFDA

- Reduced submission docs & eased decentralized-trial rules from Jul 2026
- Revised AI/ML medical device guidelines (Class II/III CADe/CADx), Aug 2025
- ICH-aligned since 2018 — fast IND review (~14 days under CTN fast-track)

Takeaways for Sites

Real gains — with real questions sites should keep asking

THE UPSIDE

- Less manual entry — data flows from source systems, not re-keyed by coordinators
- Faster query resolution and cleaner audit trails via live anomaly detection
- Shorter development timelines industry-wide (projected 30–40% over 2–5 yrs)

THE CAVEATS

- Data governance & consent — continuous EHR-to-sponsor feeds raise new local privacy questions
- Workload can shift, not disappear — new tools mean new SOPs to learn
- Regional regulatory readiness varies — this is directional, not yet universal across Asia

Closing line: AI flags anomalies — PIs and coordinators still adjudicate them. The technology changes the workflow, not the site's role as the trusted human layer around the patient.

Thank You

For queries, write to ***aritra.bhowmik@cognizant.com***