



Reimagining clinical development through intelligent automation

PW 18



**Limitless possibilities.
Real results.**

Welcome

Reimagining clinical development through intelligent automation

Presented by:



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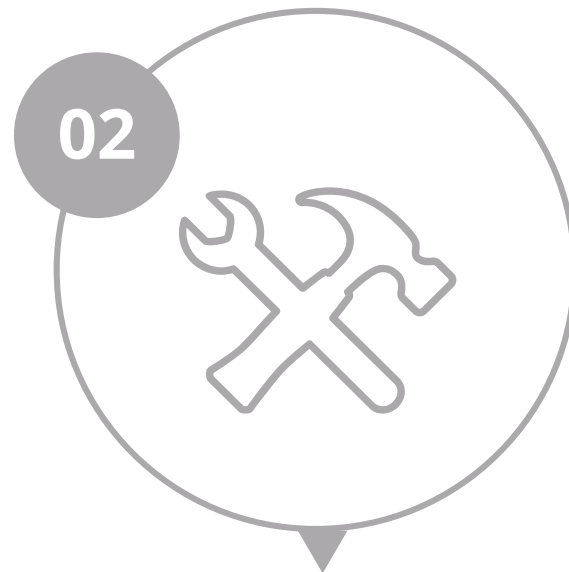
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Today's discussion

Leveraging the power of connected data to substantially increase speed to market and compliance



Riddle



Reimagine



Build



Transform

Riddle

Long cycle time and low predictability of outcome



10,000
compounds



Probability (transition)



Cycle time (years)



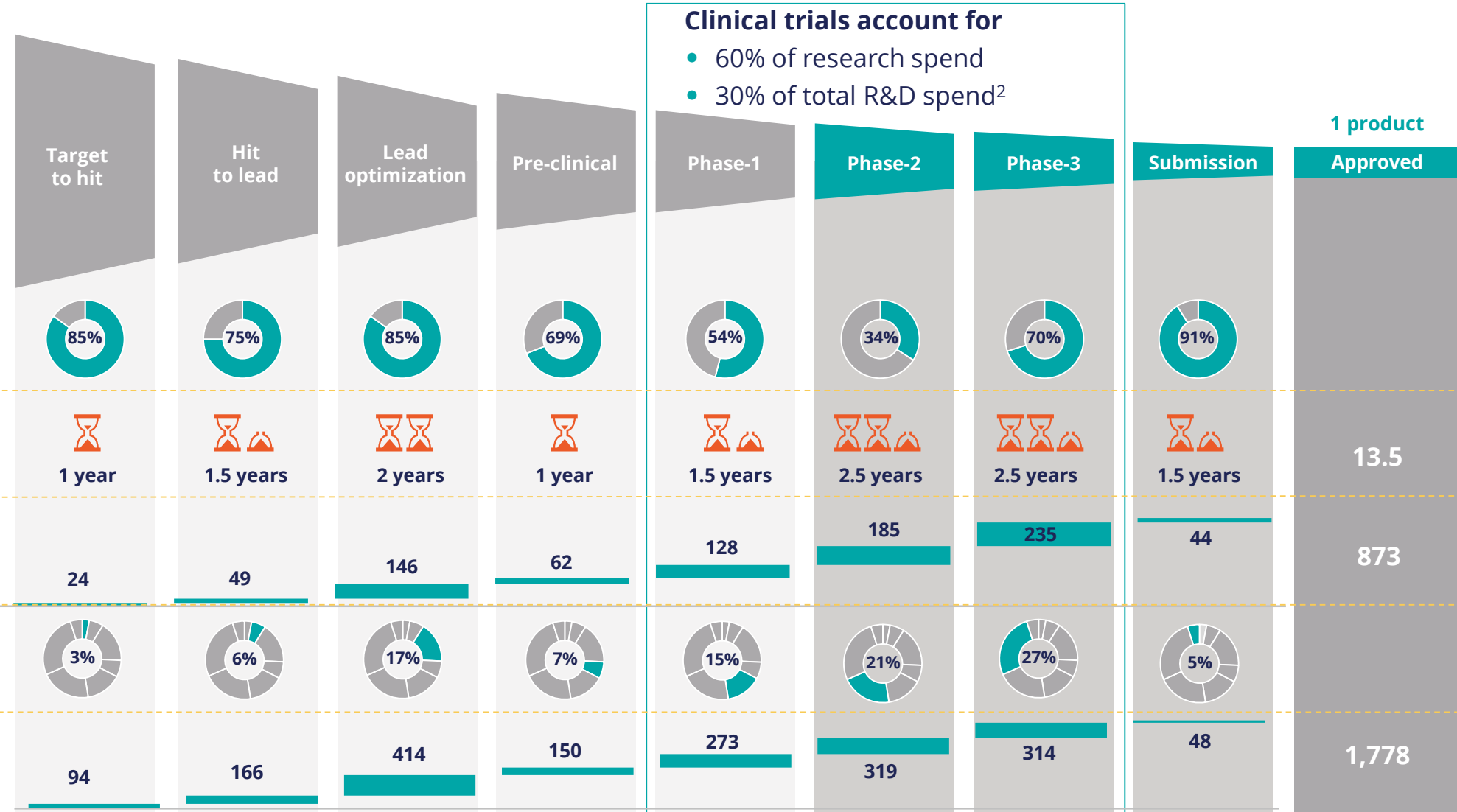
Out of pocket cost per launch (\$m)



% total cost per NME



Cost per launch (\$m)¹



Source: *Nature Reviews Drug Discovery* 9, 203-214 (March 2010) based on a set of industry-appropriate R&D assumptions (industry benchmarks and data from Eli Lilly and Company)

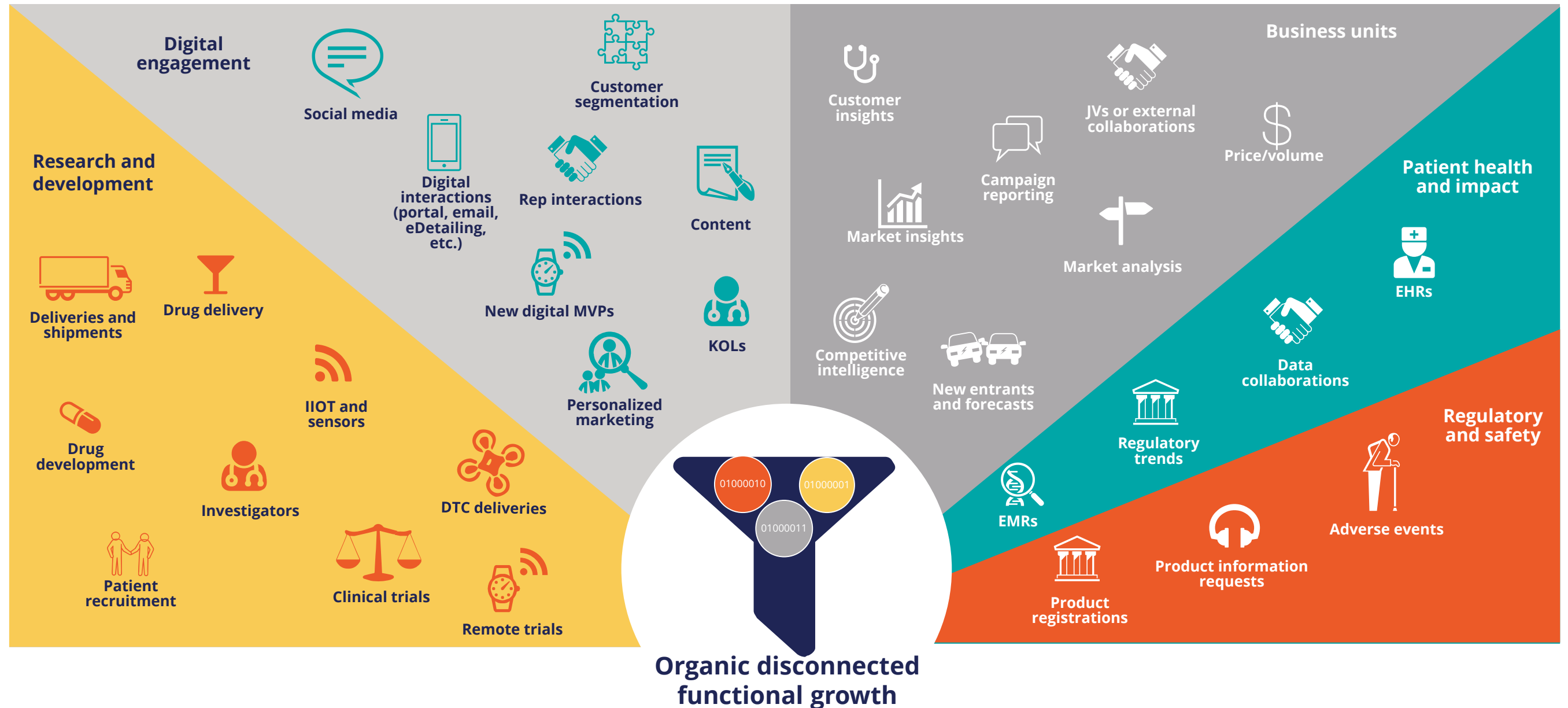
¹Capitalized at 11% cost of capital.

²Source: Goldman Sachs.

Riddle



Data distributed across too many sources, in too many functions



Riddle



The process conundrum ... disconnected data does not deliver

Data disconnected from process, people or IT infrastructure does not deliver the *right outcome* at the *right time*



Current misconceptions on data

"The data is too private to move or manage centrally ..."

"There is no organization structure focused on cross-functional capabilities ..."

"We have all the data, it is just not connected ..."

"We do not know our existing data assets ..."

Current issues with new tools

"We have barely captured ROI out of the existing systems ..."

"Today, we do not know everything that we have or that we need to innovate ..."

"It will take 18 months to get started ..."

"It will take \$50m just to get the systems in place ..."



Building and futureproofing your business by asking better questions

"What are the business questions we are looking to solve ..."

"We need to better use new analytical techniques such as AI/machine learning ..."

"To have the best insights, we need to collaborate internally ..."

"How do we deliver a user experience that allows real-time decision-making?"

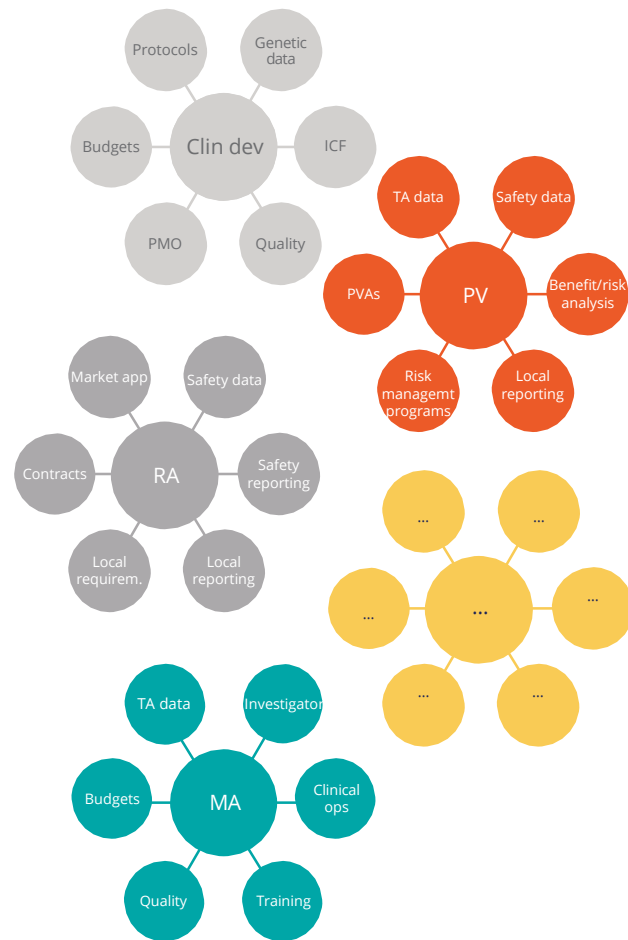
HOW? Focus on the *data* and determine *when, where* and *why* do YOU need it



Data becomes the digital currency for innovation, quality and speed to market

Point solutions

Rapidly evolved leading to siloed and isolated data



Data

Intelligent automation and innovation

Dissolve siloed/isolated data via a process driven platform

Process

- E2E digital business and compliance processes
- Real-time process design/redesign
- Integrated data reporting
- Enterprise to operations

Platform

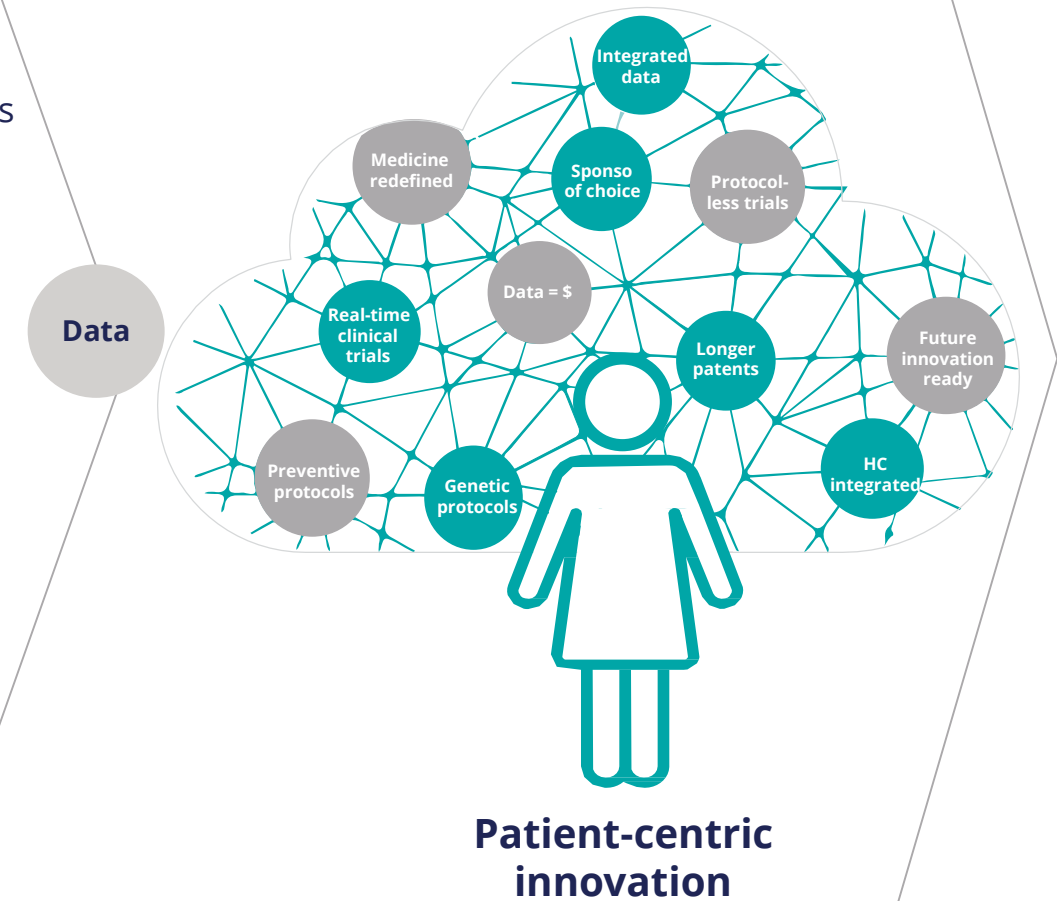
- Process-driven intelligent automation
- Wraps around existing point solutions
- Increase in AI maturity/predictability
- Process-driven intelligent reporting

Innovation

- Clinical data collection requires less patient effort
- Wearables
- Quick integration of emerging technologies into defined processes

Supra-platform digital aggregation

Real-time clinical trials of the future



Reimagine

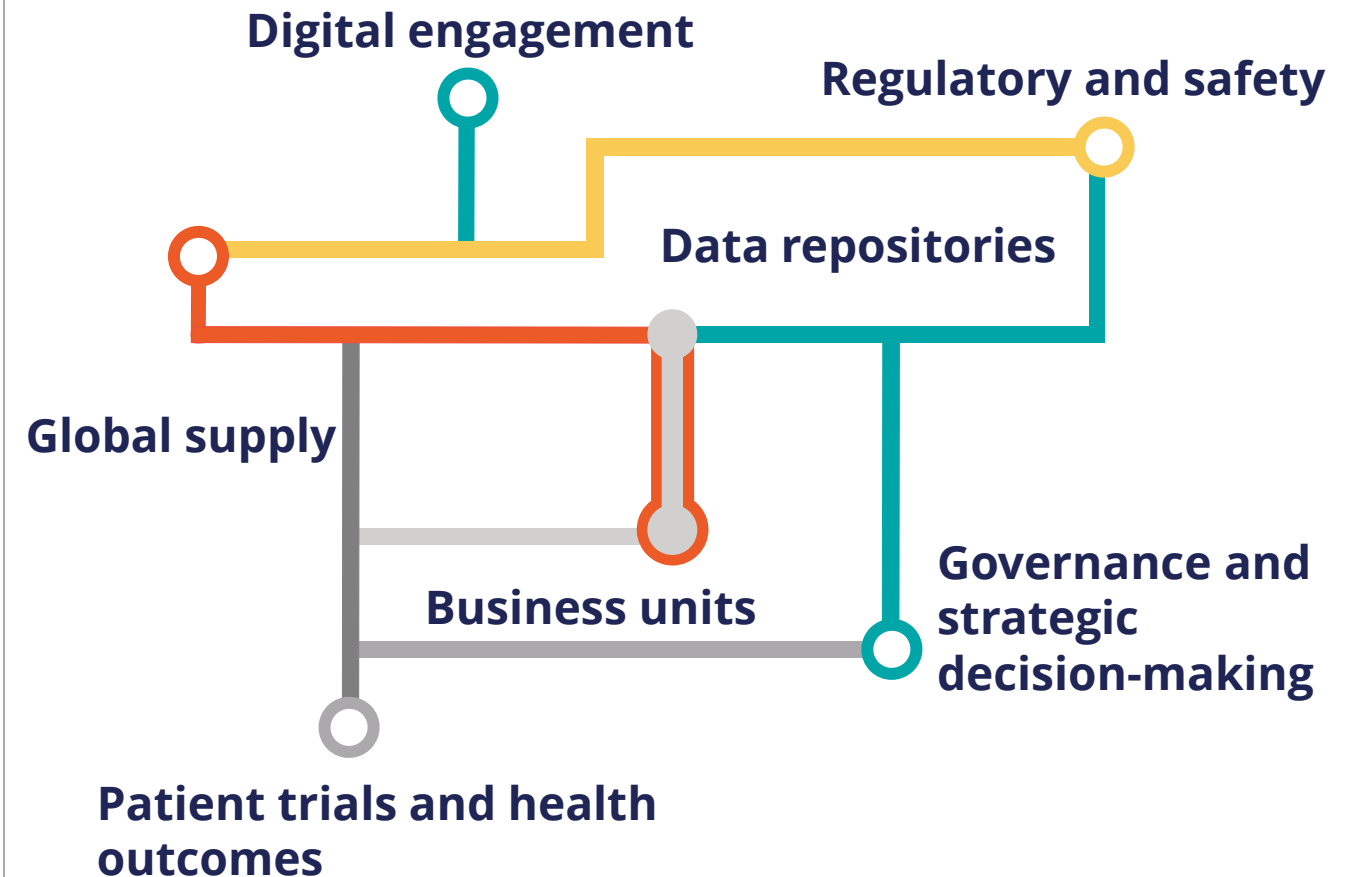
Integrate and enable data as a currency



Integrate organization-wide data in silos



To use that data for the purpose of *connectivity*

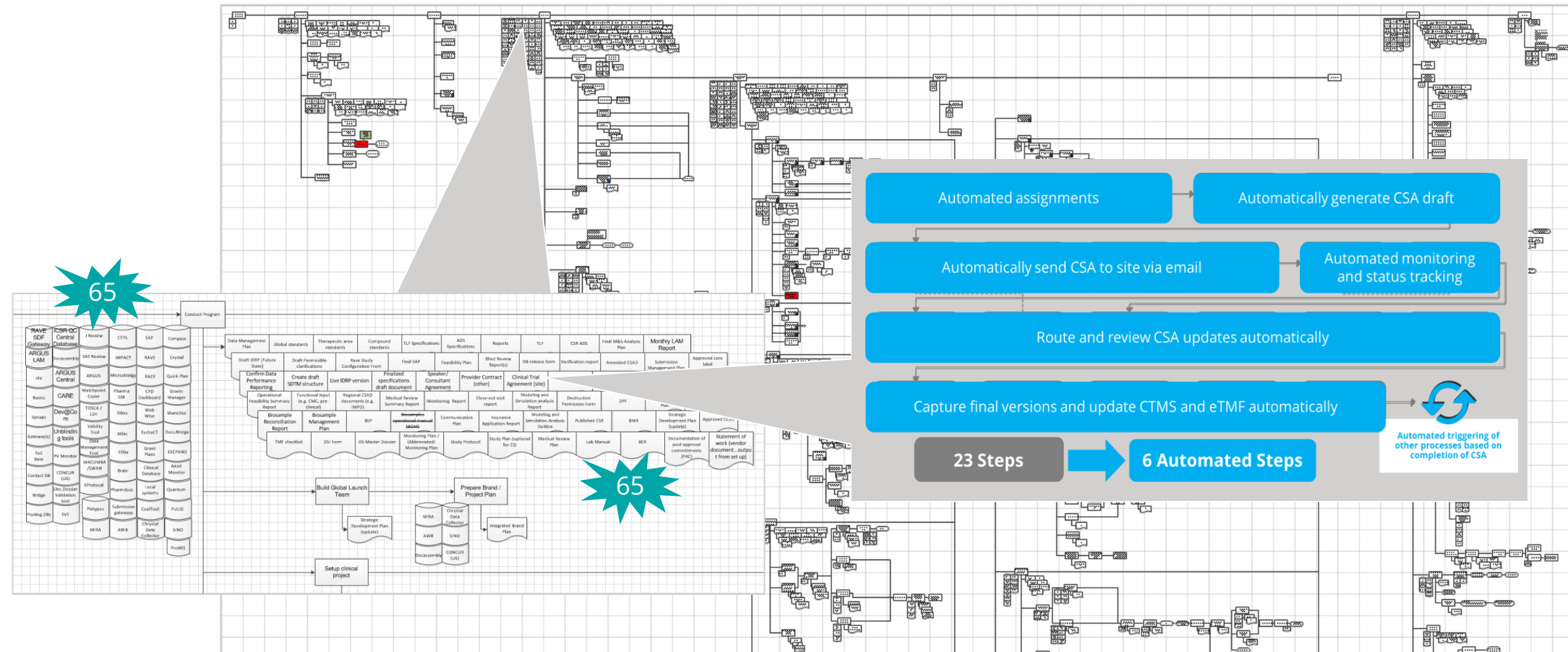


Reimagine

Better platforming enables easier integration of innovative technology



Process landscape



Optimizing data currency



Per data field: 15,000 hours returned to end user to generated value-add activities



Per data field: over \$1m in financial savings yearly, allowing for re-investment



Inconsistent patient or investigator data affecting quality/care to patients

Build

The journey to intelligent process automation

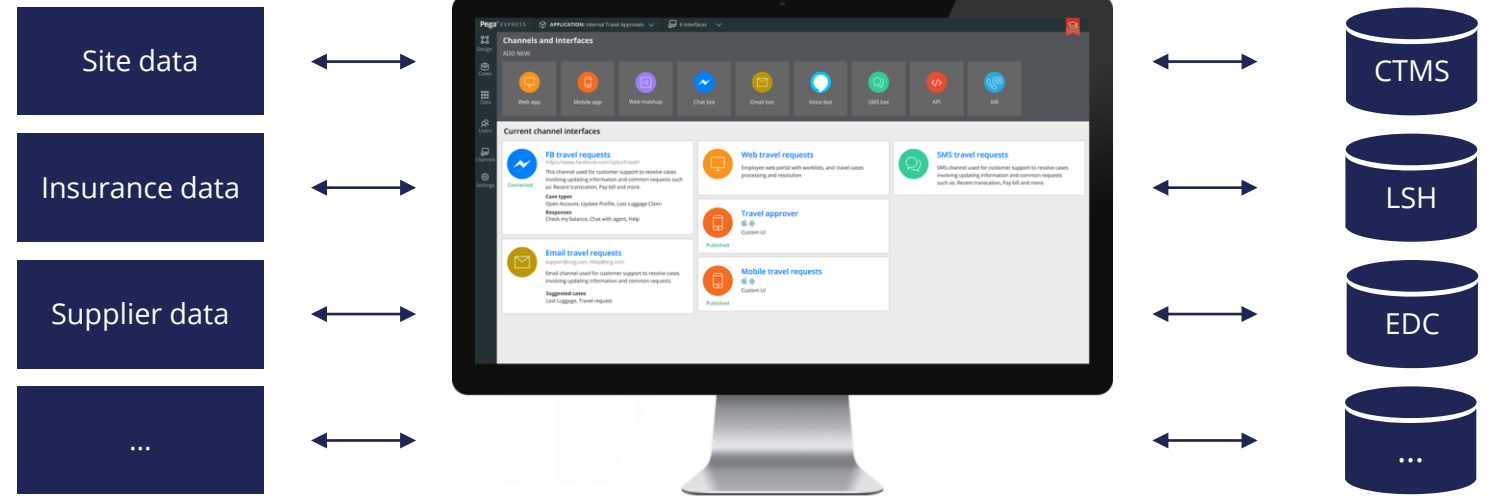


1

Utilize platform technology

The platform enables you to:

- Connect your **data** and **systems** into a **process-centric model**
- Automate processes to **improve efficiency** and **reduce time** to market
- Gain **oversight** with real-time reporting and dashboards
- Manage **risk and quality holistically** across the portfolio
- Achieve **continuous inspection readiness**
- Enable **quick integration of emerging technologies** into defined processes



2

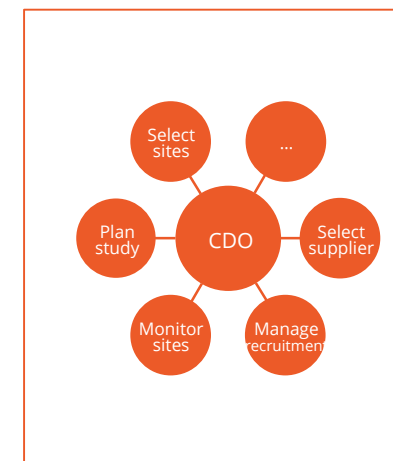
Start small and scale up over time

- **Start with identifying process areas that demonstrate high value-add** of intelligent process automation
- Add and connect additional data, systems and processes to **leverage integration synergies** and seize the full potential of intelligent process automation
- **Scale** across your organization
- Enable **usability and accessibility** for users using mobile devices
- **Securely open up the platform** for collaboration with external parties (patients, suppliers, sites)

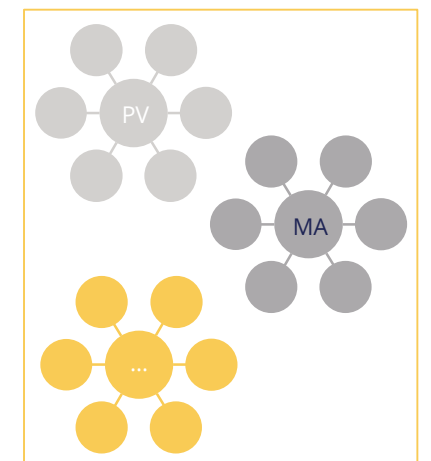
Start with one process



Scale within CDO

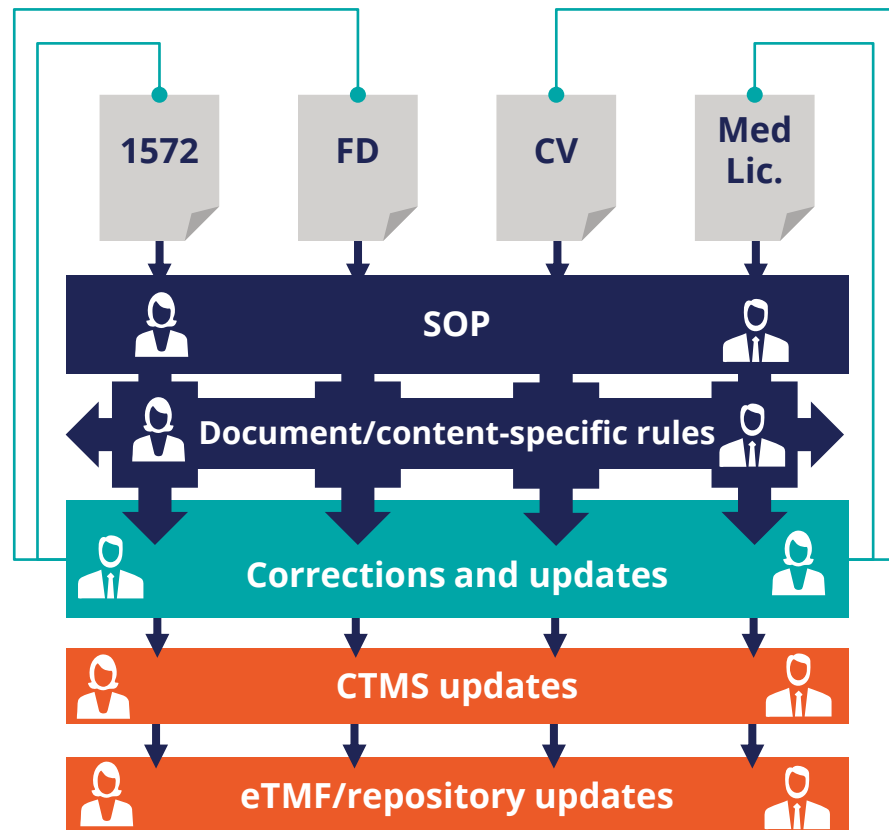


Scale across R&D



Build

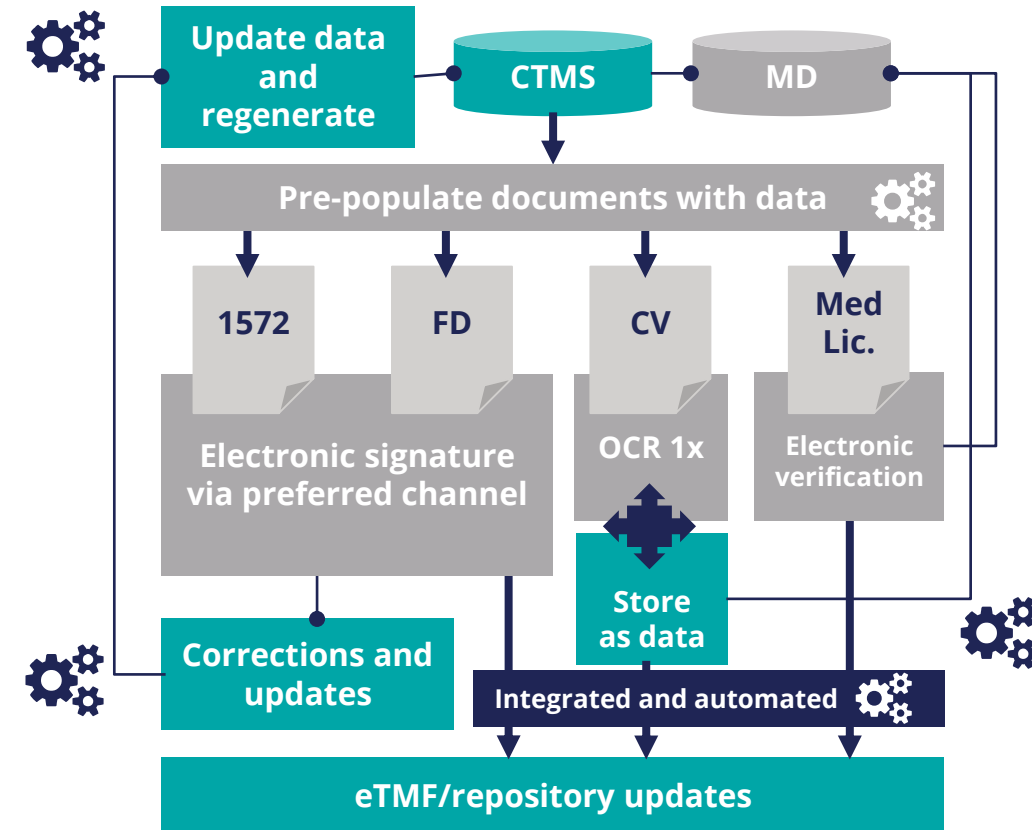
An example of harmonized infrastructure, people and process



Manual/siloed processes: Primarily regulated activities are documented (<50% of total R&D activities).

Fragmented IT systems: The user journey is disrupted by multiple IT solutions with limited connectivity.

Compliance-driven approach: Activities are organized to produce compliance documents.



End-to-end, event-driven process management (including regulated and non-regulated activities)

Workflow platform (connecting fragmented IT and providing a single-user interface)

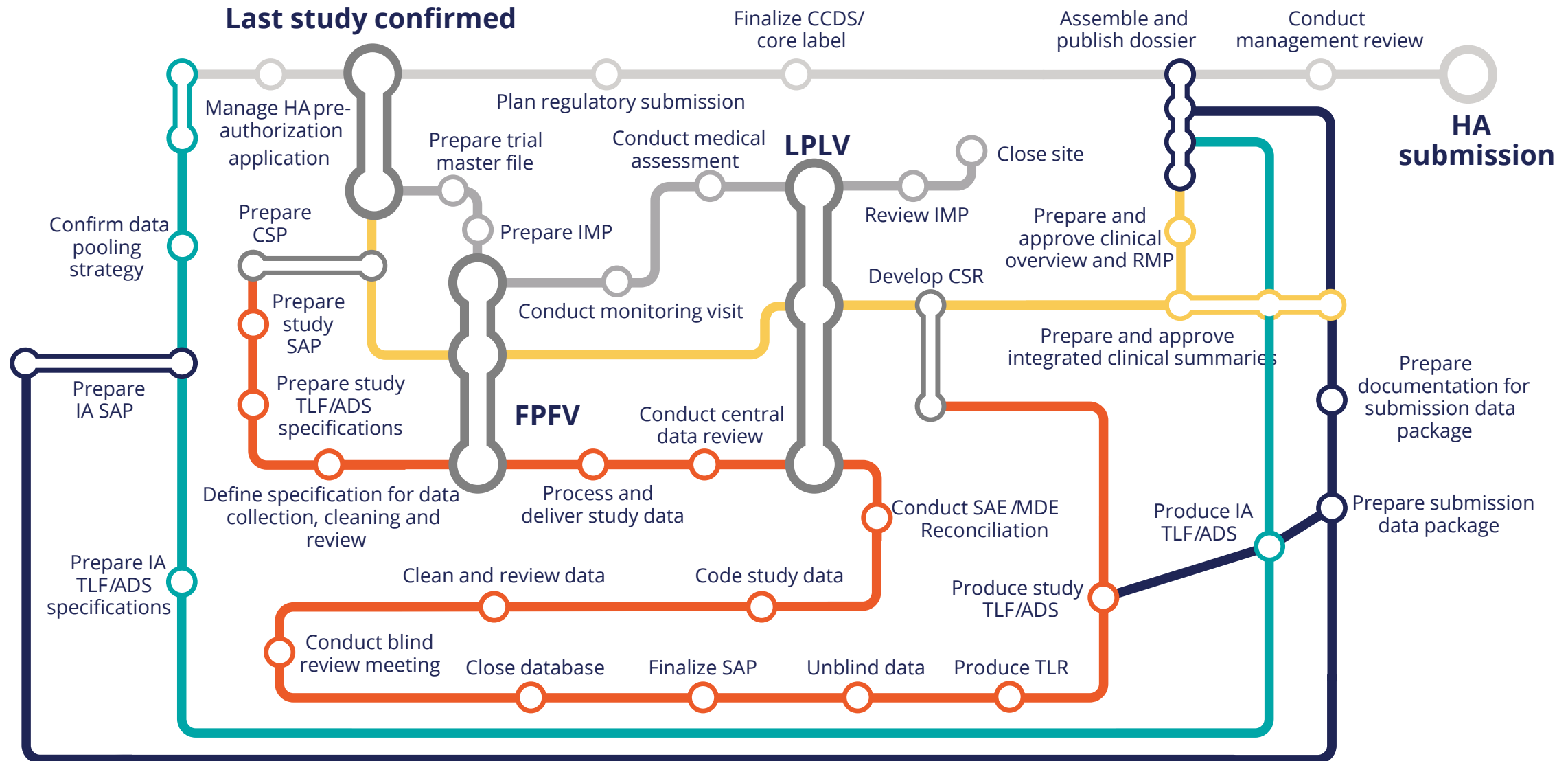
Consistent data stream (enabling real-time risk monitoring and mitigation)

Study start-up: Today vs. 20??



Harmonized infrastructure, people and process model

Cross-functional, organization-wide connectivity

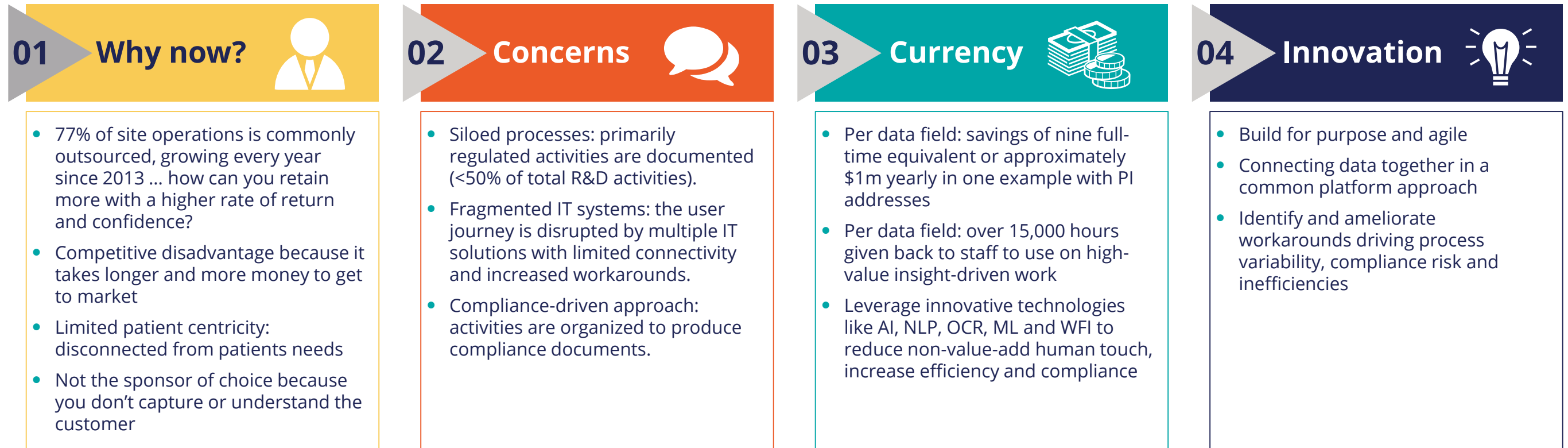


Transform



Data becomes a currency/asset to drive speed to market and innovation

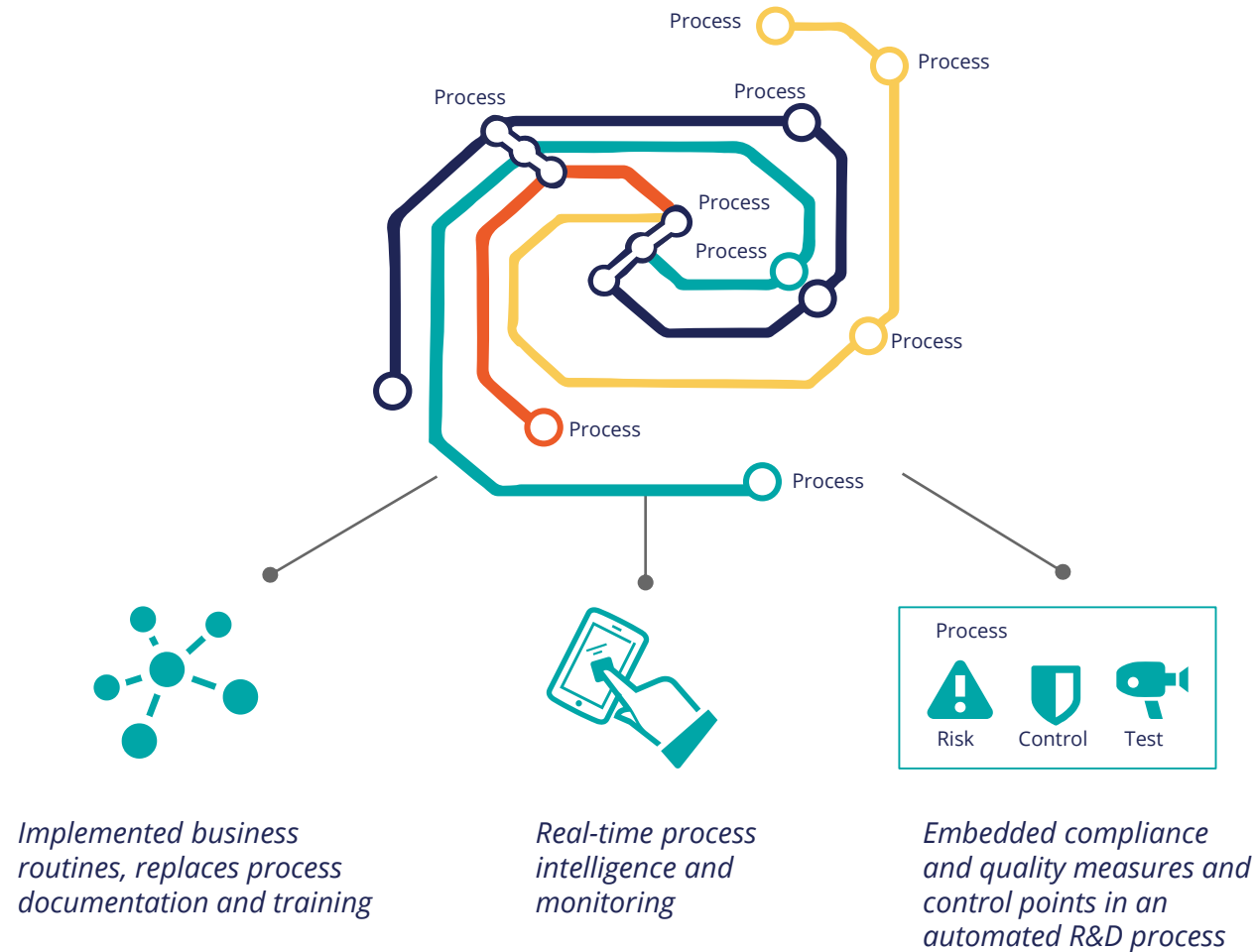
- Knowing the importance of data to your programs, patients and health authorities globally will optimize and futureproof your digital currency through E2E process design, UX and an IT-enabled platform.
- End-user, process-driven, just-in-time activities in a single scalable interface eliminates redundancies across various system (e.g., CTMS, RAVE, RAS, LMS, ARGUS, ARISG).



Transform

Contained process governance manages the data, risk and compliance

What is the future? *Reuse, not recreate*



Outcomes and benefits

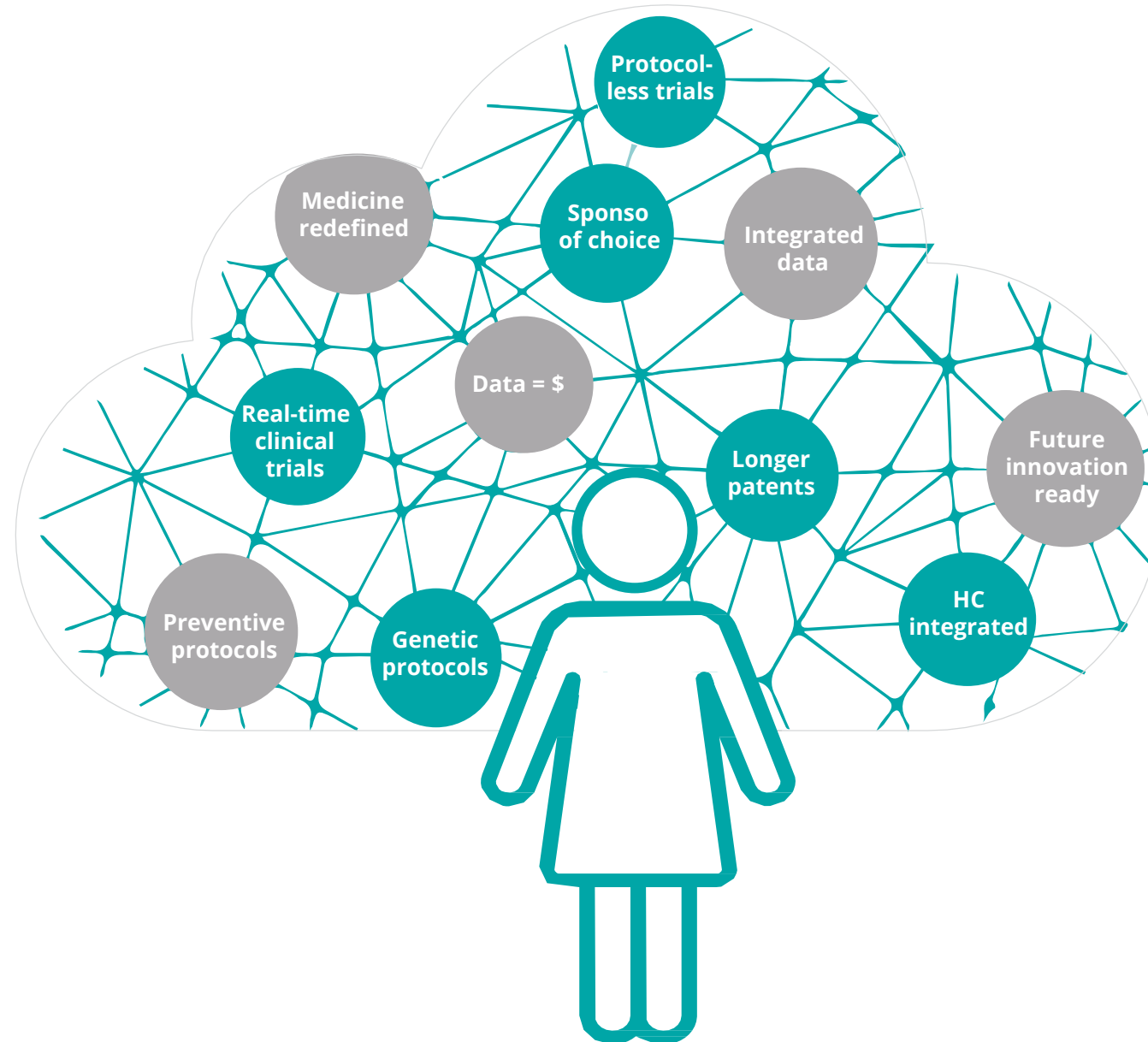
- Data and process are entered **once** and **delivered just in time** via automation and governance.
- Automated activities are **delivered just in time** to the right resource.
- **Outputs** are delivered just in time with the correct data.
- **Active process guidance** reduces training needs and retains internal IP.
- **Real-time process monitoring** and exception handling.
- **Efficient and compliant** design of business activities is managed by the business.
- Implementation documentation of the business routines and rules and audit logs confirm **inspection readiness**.

[People] X [Infrastructure] X [Process] = *Offensive future*



Transform

Transforming business operations enables better patient and customer experiences



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