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Health Sciences

Real World Evidence: Where are we heading?

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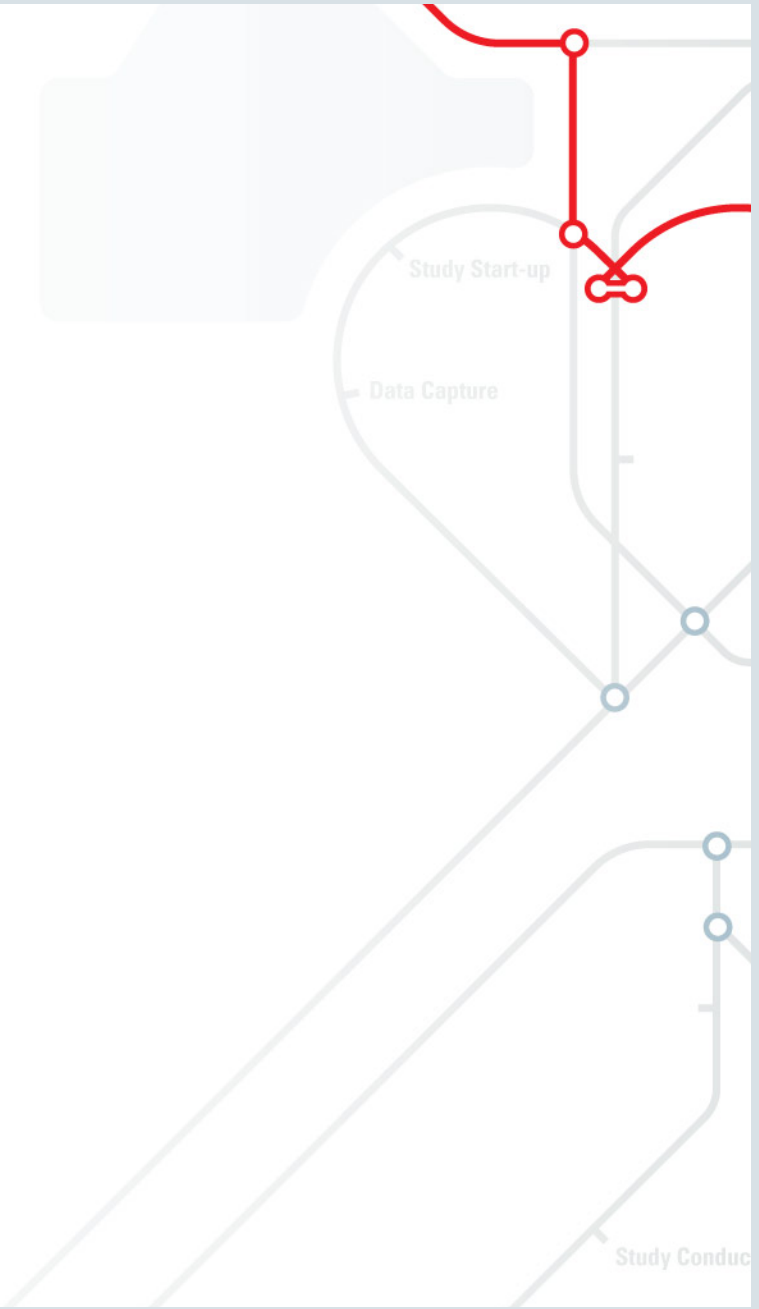
Agenda

1. Where are we today?
2. Where are we heading?
3. Planning for the future
4. Final thoughts



"…pharmacokinetics (PK) and pharmacodynamics (PD) of many drugs are also subject to circadian variations, profoundly affecting their efficacy and tolerability. Understanding how circadian rhythms influence drug PK, PD and toxicity might significantly improve treatment efficacy and decrease related side effects[1]"

"Breast cancer (BC) is a heterogeneous disease where each OncoOmics approach needs to be fully understood as a part of a complex network. Therefore, the main objective of this study was to analyze genetic alterations, signaling pathways, protein-protein interaction networks, protein expression, dependency maps and enrichment maps in 230 previously prioritized genes.. According to the Open Targets Platform, there are 111 drugs that are currently being analyzed in 3151 clinical trials in 39 genes. Lastly, there are more than 800 clinical annotations associated with 94 genes in BC pharmacogenomics[2]."

"Data sources for real-world evidence include electronic health records, insurance claims and billing, registries or on-site medical chart review. However, information about how patients feel and function, as captured directly from patients themselves, is often missing[1]. As pressures from legislation, international regulatory authorities and patient groups promote more patient-centric drug development and evidence generation, attention is now turning to the role of patient-reported outcomes (PROs) to provide the patient perspective in real-world data sets[3]."

[1]*https://doi.org/10.1111/bph.14712*
[2]*https://doi.org/10.1101/638866*
[3]*doi: 10.1038/d41573-019-00088-7*

Real World Data

Today

- EDC
- Central Labs
- IxR
- Safety
- CTMS
- PK/PD
- …

Tomorrow

- EHR
- Device/Sensor
- ePRO
- Claims & Billing
- Registries
- ‘Omics
- …

Potential

- Scientific Publications
- Social Media
- Weather
- Census
- …

Clinical, Scientific and Healthcare Convergence

Trial Planning & Budgeting

Randomization & Supplies

Data Management

CTMS

Biogenetics

EDC

Real World Evidence

Clinical Research

‘Omics

EHR

mHealth

Quality Metrics

Patient Care

Population Health

Precision Medicine

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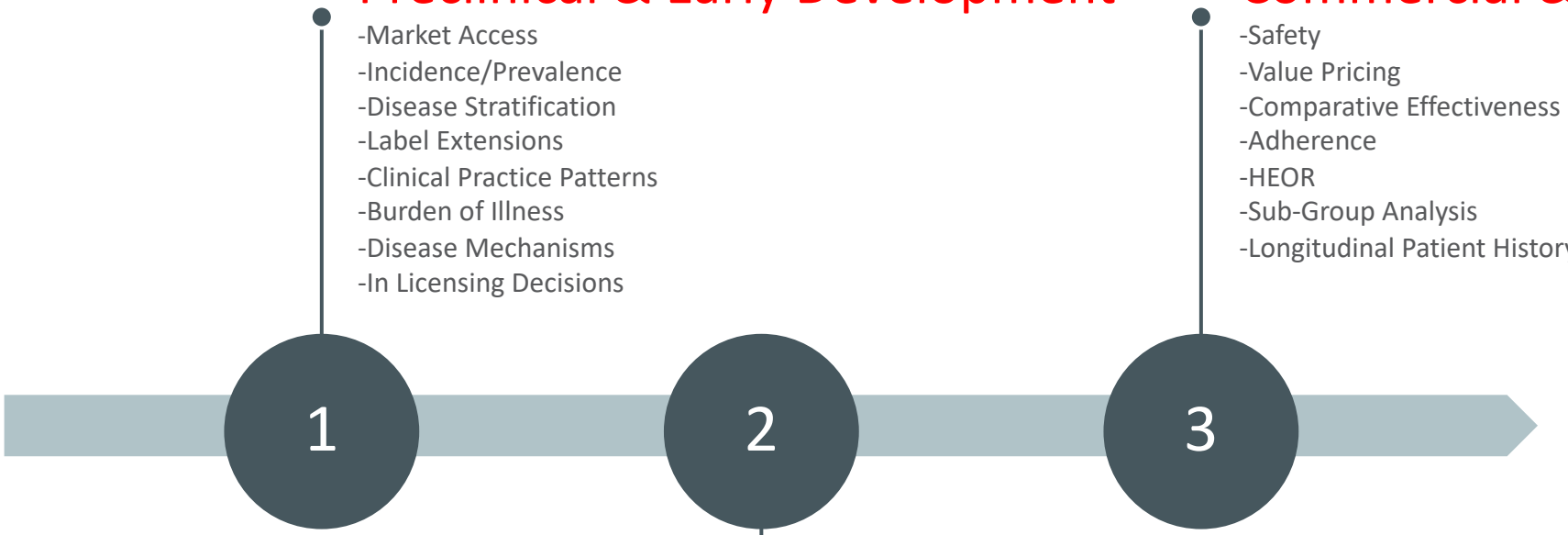
Use Cases Across Drug Development



Preclinical & Early Development

-Market Access
-Incidence/Prevalence
-Disease Stratification
-Label Extensions
-Clinical Practice Patterns
-Burden of Illness
-Disease Mechanisms
-In Licensing Decisions

Development

-CRF Population Automation
-mHealth Devices/Sensors
-Protocol Feasibility
-Patient Recruitment
-Drug Development Tool Identification

Commercial & Post Marketing

-Safety
-Value Pricing
-Comparative Effectiveness
-Adherence
-HEOR
-Sub-Group Analysis
-Longitudinal Patient History and Experience

Barriers

Multiple data models
Multiple, incompatible data models create data aggregation complexities.

Inconsistent terminology
Inconsistent terms, semantics and dictionaries make data aggregation and interpretation challenging.

Longitudinally fragmented, disparate data sets
Chronologically fragmented data from multiple sources diltues the value of a holistic patient profile.

Governance, privacy and consent
Regional variations in data privacy regulations prevent creations and analysis of large scale datasets.

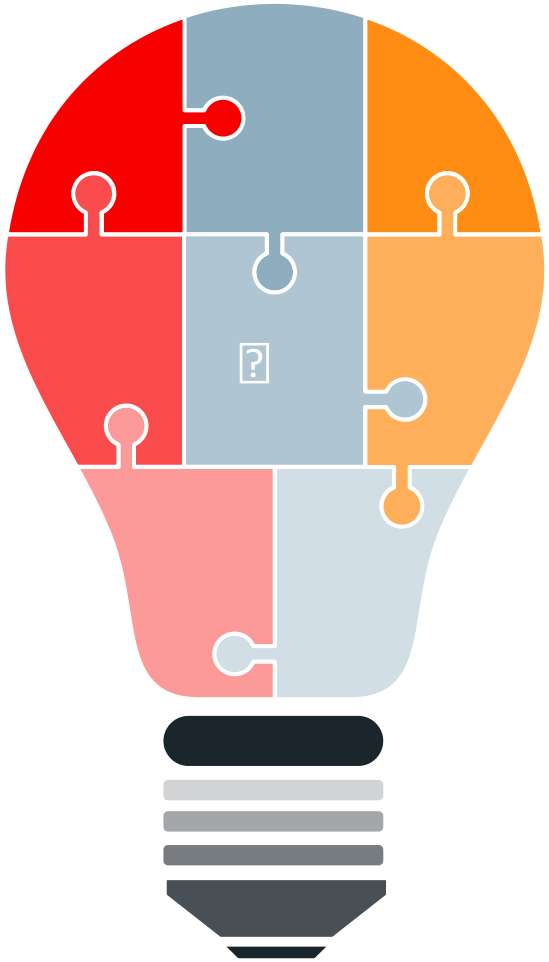
Technology integration
Multiple informatics systems create data integration explosion.

Data quality[1]
Data quality issues around completeness, correctness, concordance, plausibility, currency.

Opportunities

Real World Data
Digital data streams, structured and unstructured, machine readable/images growing at exponential scale.

Scientific Data and Bioinformatics
Acquiring genetic, protein, hormone and metabolic information using scientific modelling and simulation



Population Health and Precision Medicine
Complete sequencing of the genome, exome, proteome, transcriptome and metabolome contextualize patient/population variation

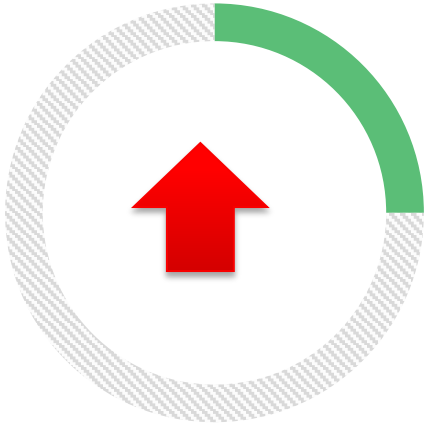
Interpretation and Analytics
Artificial intelligence, machine learning and data mining allow for analysis and interpretation of unstructured data in addition to statistical analysis.

Clinical R&D: Value

Reduced

Study setup timelines

Integrating EHR to pre-populate the CRF with qualified subjects



Increased

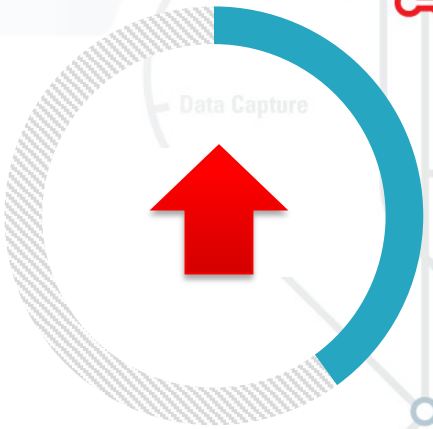
Data quality

Transcription errors and data entry burden reduced.

Decreased

Cost clinical trial costs

Smaller clinical trials, more endpoints, higher clinical granularity

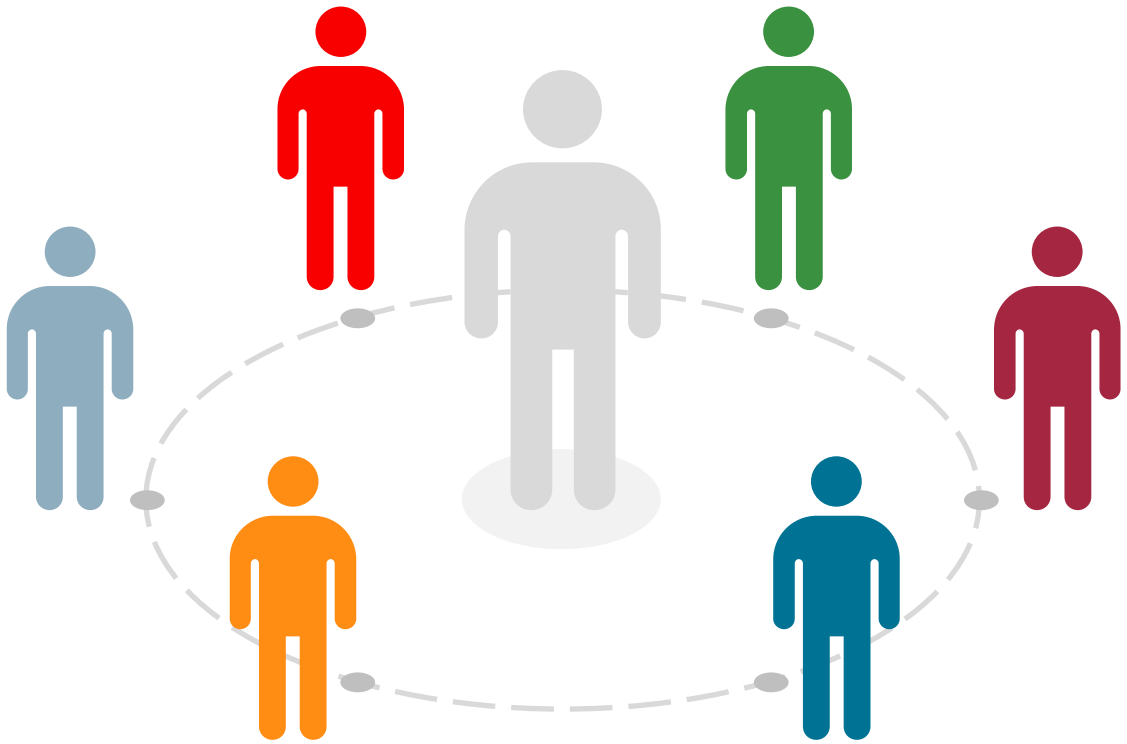


Increased

Patient Value

Cost of treatment optimized to patient response.

Impact



Patient
Any new technology must consider the patient at the centre of the implementation.

Healthcare Professional
Will need awareness and enablement to understand, adopt and benefit from new technology used to share data.

Regulator
Will need to provide guidance and consent frameworks to support secondary use of clinical data addressing privacy and security concerns.

Sponsor
Will have to ensure patient safety, demonstrate clinical efficacy and trial integrity whilst reducing cost time and risk.

Preparing for 2025

Patient Centricity

Driven by genetics

Precision to predictive treatment[2]

Longevity, disease and reproductive healthcare

Data Convergence

Genetics is the ultimate Big Data problem – “Sequencing Billions of individuals”

Discovery research & development

Informed consent, privacy, security and regulatory controls

Technology Platforms

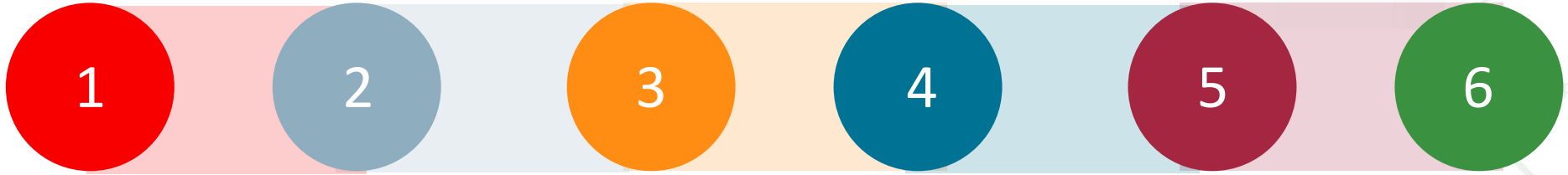
Alpha Zero[1] - Pattern recognition to self learning

Predictive genetics

Exponential rate of change of technology across biology and silicon platforms

[1]https://deepmind.com/blog/alphazero-shedding-new-light-grand-games-chess-shogi-and-go/
[2]https://www.nytimes.com/2019/04/10/opinion/genetic-testing-privacy.html

Transformational Imperatives



Simplify
Simplify technology, applications and processes with a cloud service delivery model

Unify
Create a single source of truth for data, definitions and processes

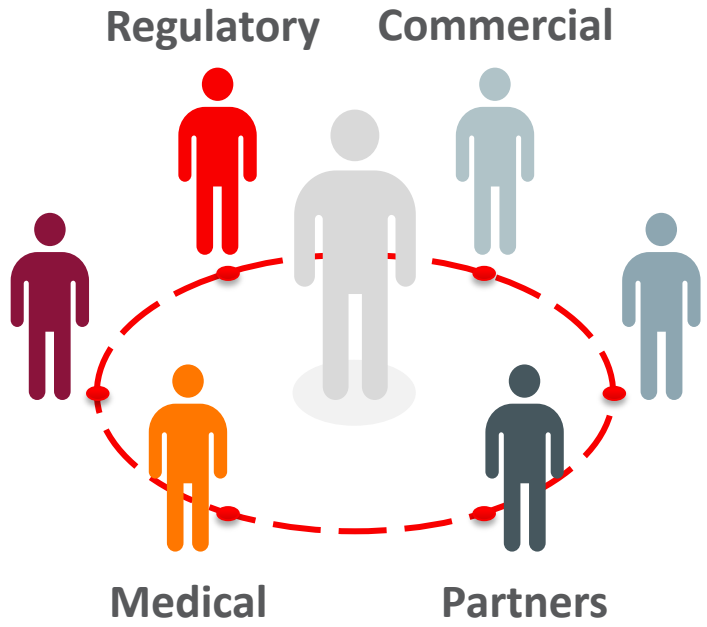
Platform ecosystem
Develop a collaborative partnering ecosystem that innovates new capabilities, processes and insights

Platform scale
Proactively manage the size and scale of growing data streams to develop new insights

Services
Provide new services, increase service levels and lower cost of platform services

Business Process
Debottleneck end to end business process to enable unconstrained data flow, review and analytics.

A Unified Perspective



Discovery **Development**

Data

Unified patient, science and evidence data flow across all stakeholders

Integrated Cloud

Applications & Platform Services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