

REAL WORLD DATA (RWD) AND ROADMAP TO R

SampleR PlatteR Night

August 4, 2020

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Making Research More Efficient & Strengthening the Research Life-cycle

Real World Data (RWD)

*Patient data that is collected through a variety
of sources*

Real World Evidence (RWE)

*Clinical evidence obtained from RWD
analysis*

Tonn RWD ROADMAP

International
Standards

Hospital &
Payer System

Senior
Management
Consulting

Medical
Device Trials

Payer-Plan
Risk-sharing
Agreements

Bridging gaps between clinical care and
research to improve patient lives, decrease costs,
and improve efficiency

15+ Years governing RWD
assets and advancing data
fabrics for analytics

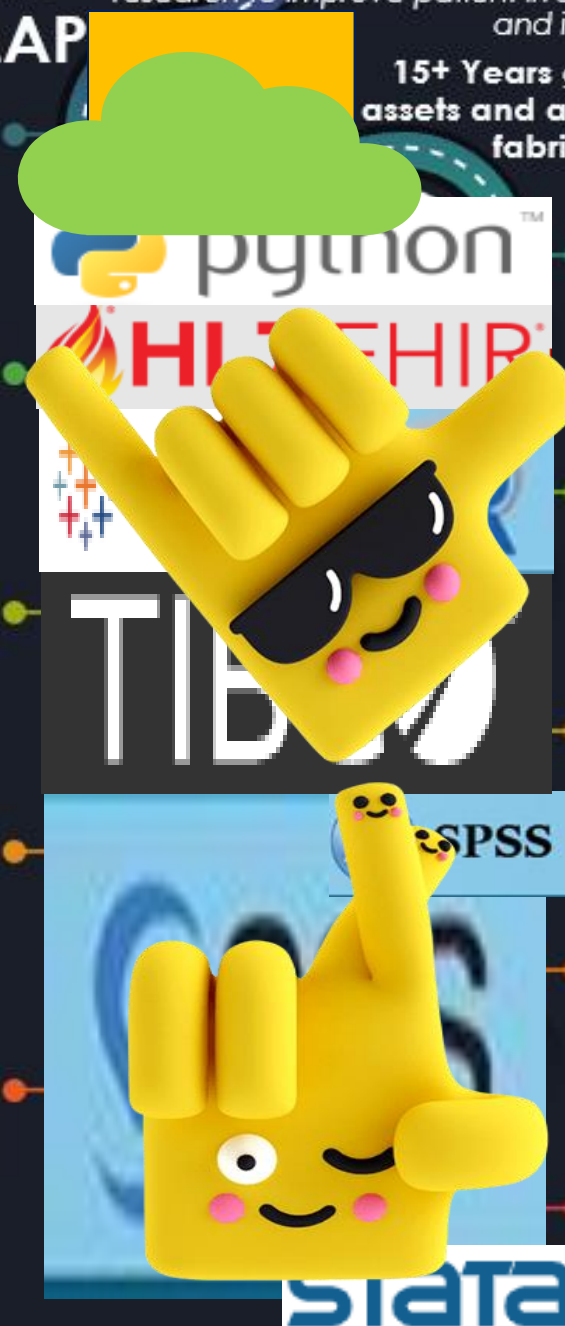
RWD & RWE

Global RA
Outcomes
Benchmarking

Neurology
Measurement &
Implementation
Science

Neurology
Pragmatic
Studies

CMS Payer &
Beneficiary



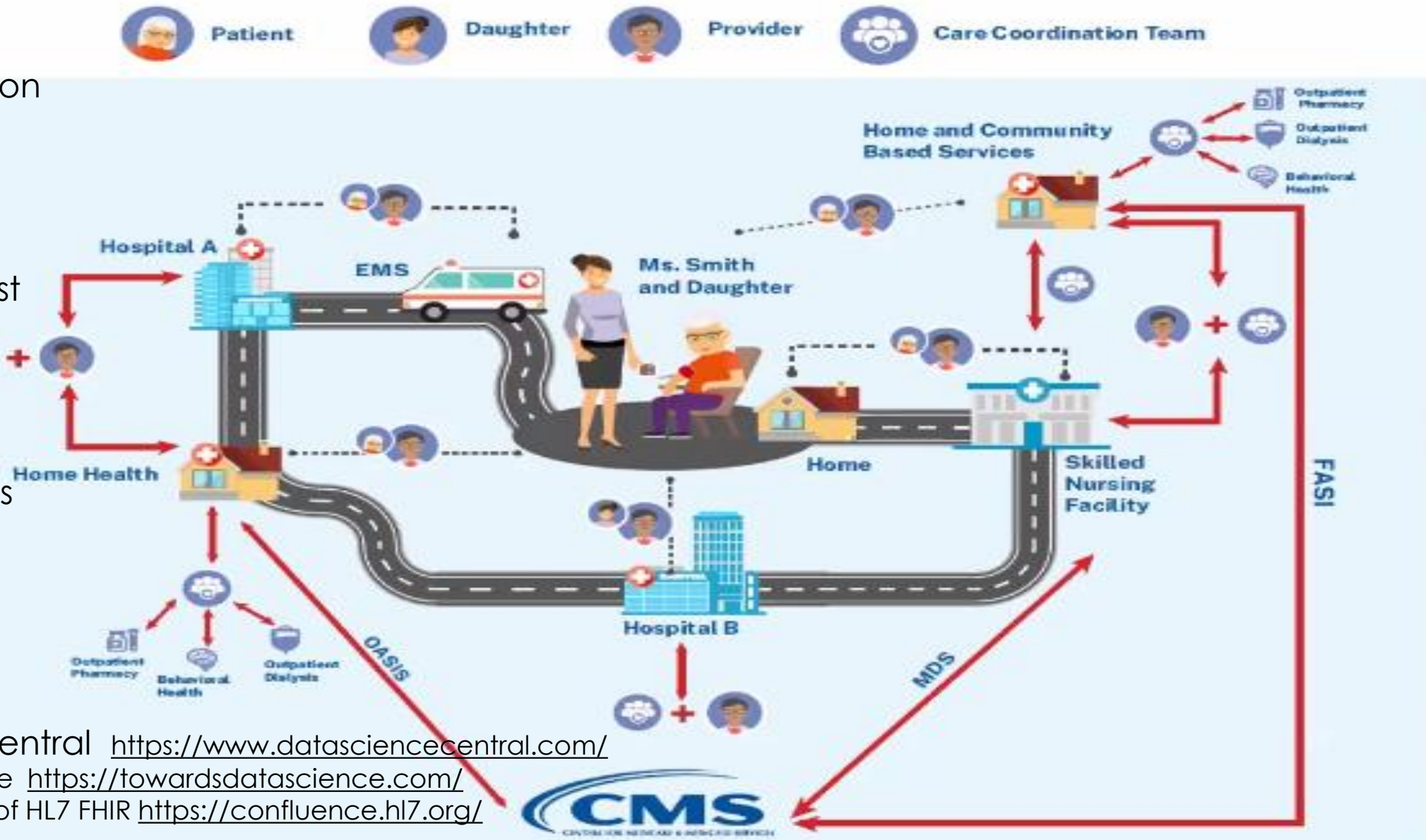


- ▶ <https://data-flair.training/blogs/data-analytics-tools/>
- ▶ <https://www.datanami.com/2020/07/10/left-for-dead-r-surges-again/>

LEFT FOR DEAD, R SURGES AGAIN

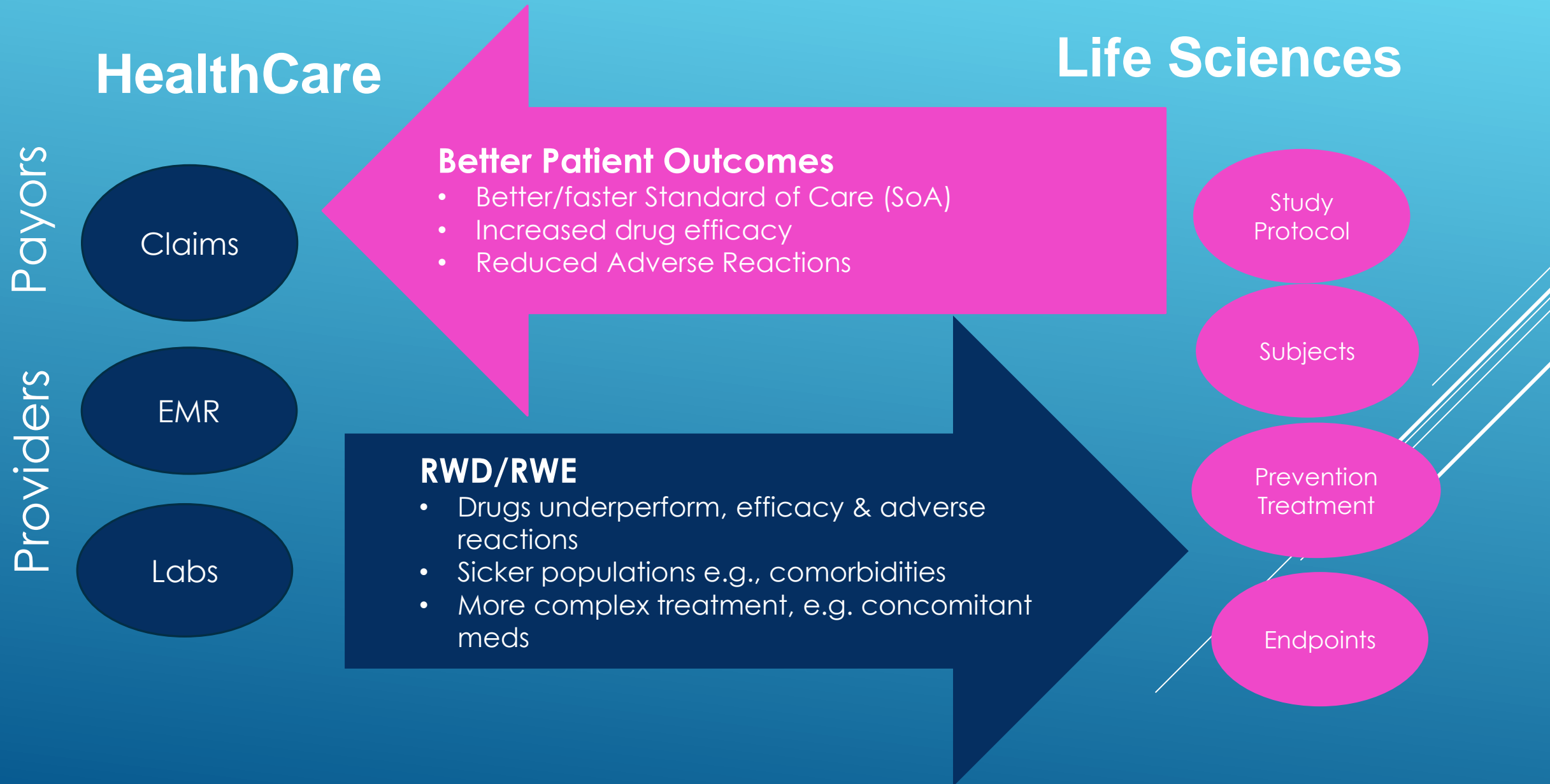
Post-Acute Care (PAC) Patients Have Complex Situations

- Poor communication across care providers, including outpatient
- Increased cost and provider burden
- Reliance on patient recall during periods of high stress



Data Science Central <https://www.datasciencecentral.com/>
Toward Data Science <https://towardsdatascience.com/>
Confluences pages of HL7 FHIR <https://confluence.hl7.org/>

WHY SHARE, PARTNER, ACQUIRE RWD?



COMPLEXITY: TRANSACTIONAL VERSUS LONGITUDINAL

HealthCare

Life Sciences

SNOMED
MedDRA
LOINC
ICD-10 / CPT
NCI Controlled Terminology

Medical Dictionaries and Taxonomies

WHO DRUG
NLM Mesh
ClinicalTrial.gov
UMLS

Claims

- Cigna
- Humana
- Optum
- IQVIA (IMS Health)
- Truven

EMR / EHR

- EPIC
- Cerner
- Meditech
- Siemens
- CPSI
- MEDHOST
- Athena Health
- Allscripts

LIMS

- Hospitals
- LabCorp
- Quest
- Independent Labs

Healthcare Data Standards

OHDSI OMOP CDM

HLL7 FHIR

Microsoft CMD-healthcare

Clinical Data Standards

CDISC CDASH, STDM, ADaM, SEND

CDISC BRIDG

Transcelerate - CDM

GAP

Protocol and SoA

- Merck
- GlaxoSmithKline (GSK)
- Johnson & Johnson
- Abbvie
- Sanofi
- Bristol Myers Squibb (BMS)
- AstraZeneca

Electronic Data Capture

- Oracle InForm
- Meddata Rave
- IBM Clinical Development
- IQVIA Clinical (Quintiles)
- Veeva Vault Clinical Suite

Data Management (DM)/Stats

- SAS, R
- Oracle Argus, DMW, CTMS
- IQVIA Clinical (Quintiles)

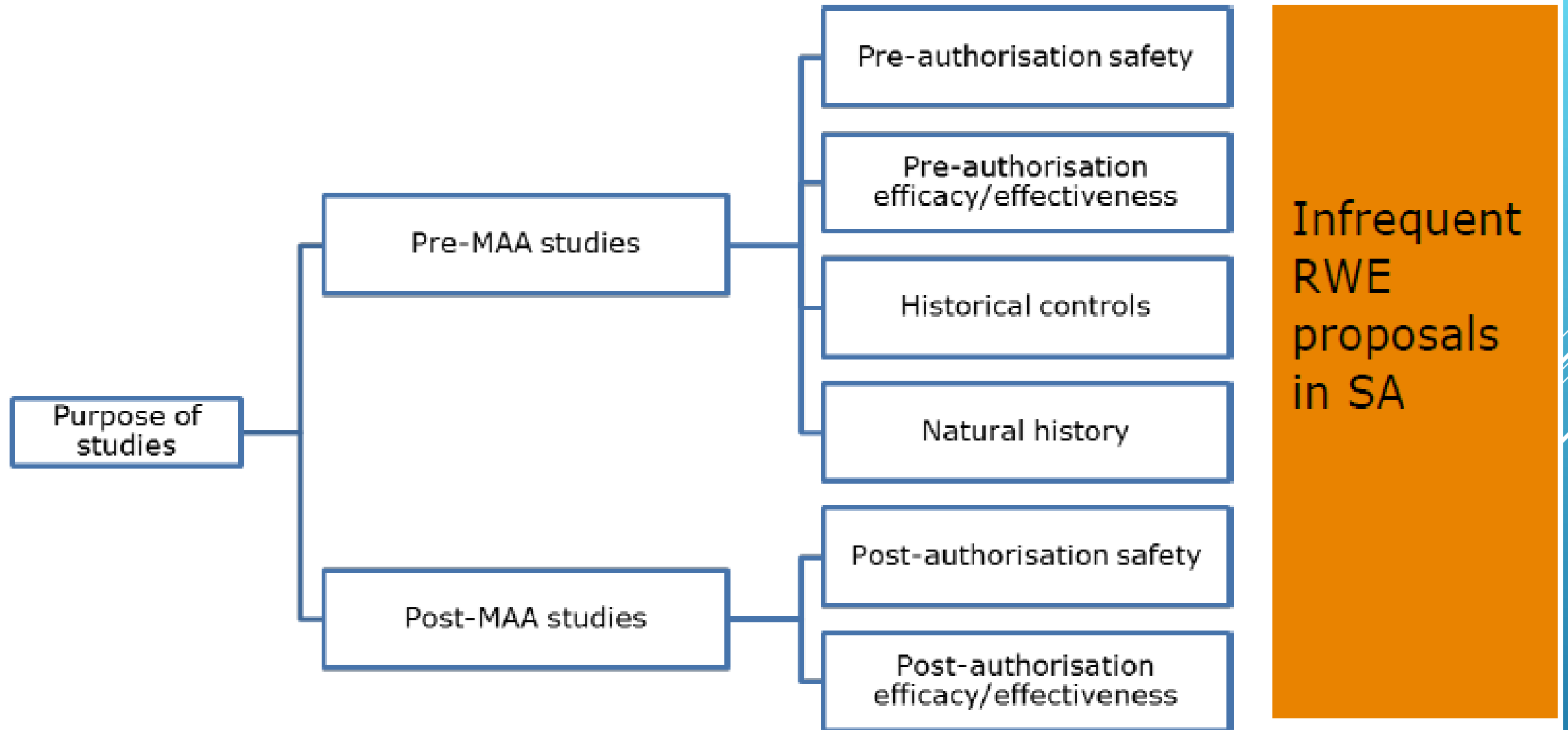
Electronic Submission

- Similar to EDC suppliers, DM
- Many additional ISVs

Legacy

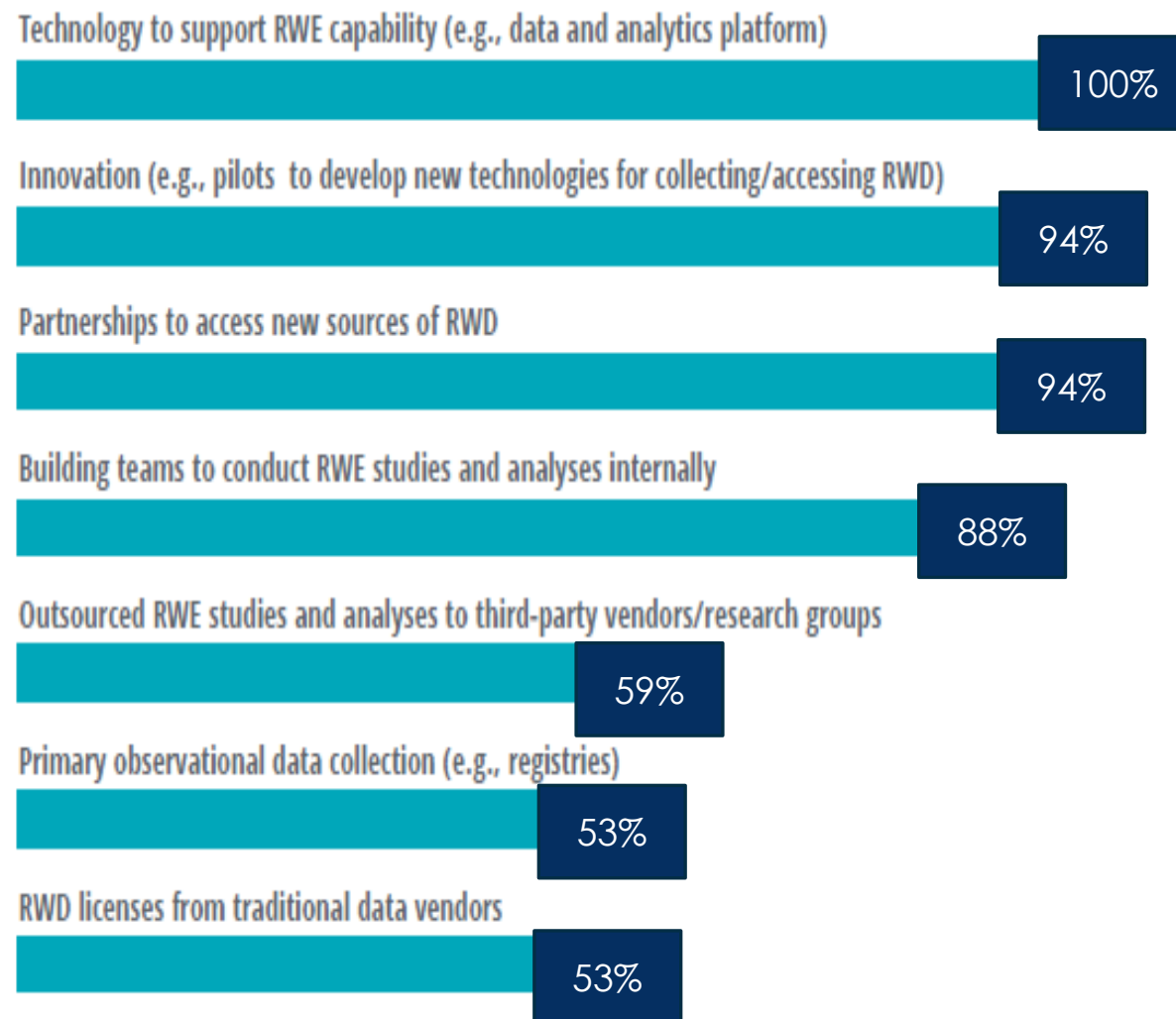
Providers
Payers

Perspective: FDA RWE Program Framework



Investments in data and analytics platforms, innovation, and partnerships are expected to increase in the next two or three years

Q: As your RWE capability evolves, how do you believe your investments and spending will change in the next two or three years? (Please select all that apply.)



Note: Total respondents = 17.

Source: Deloitte's third RWE Benchmarking Study.

RWD Governance Principles

- Accountability for High Quality Data
- Use in approved, secure, ethical way with privacy & security at core
- Optimize governance, mitigate compliance and risks, empower stakeholder

Seven Steps to Governance

- Balanced, Lean Governance
- Data Quality—Stewards
- Data Access
- Data Literacy
- Data Content
- Analytic Priorities
- Master Data Management Process

- ▶ RWD becoming a reality in Healthcare with Generation Data shaping HIT
- ▶ Research community alignment leveraging HL7 FHIR (Cures Act)
- ▶ Growing digitalization brings along modernized EHR standards and HL7 FHIR
- ▶ More effective acquisition, exchange, and use of data
- ▶ *Maturity and pace of transition* in this space varies across markets
- ▶ Several HL7 Accelerators expediting development of digital health solutions
 - ▶ *Project Argonaut* (providers to providers)
 - ▶ *DaVinci* (providers to payers)
 - ▶ *CodeX* (Oncology data)
 - ▶ *Gravity* (SDOH)

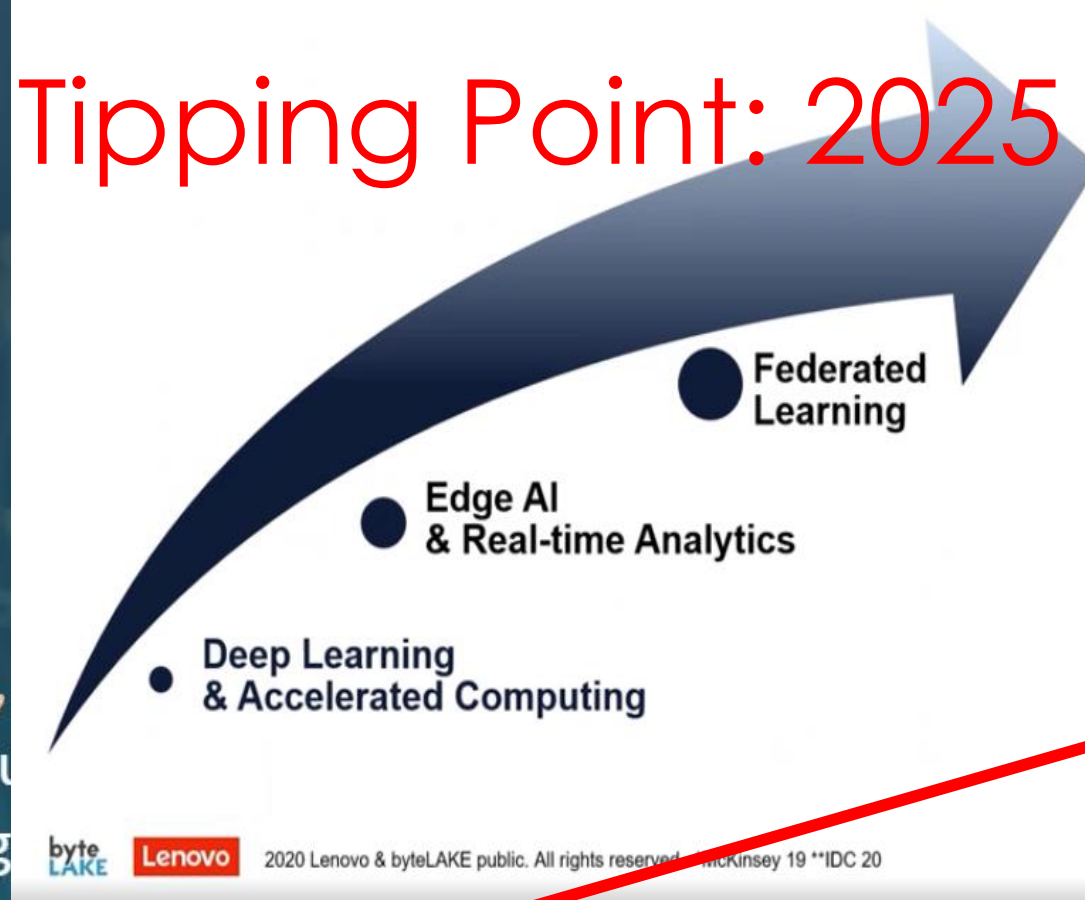
Tipping Point: 2025

RWD AND DIGITAL HEALTHCARE ENVIRONMENTS

Rising Demand for Data Fabrics 2020

“Extreme levels of **diversity**, assets are adding tremendous and data management design

Tipping Point: 2025



Edge AI
28% of AI hardware will be at the edge.*

IoT Data
41M Connected devices, generating 79ZB of data.**

This has led to a rise in demand for data fabric architectures that utilize **active metadata, semantics, AI/ML algorithms and knowledge graphs** to drive augmented data integration and data management.”

79.4 zettabytes (ZB) of data will consist of everything from **small items that burst like machine health and status as well as large unstructured data from video surveillance cameras. [International Data Corp IDC, <https://www.idc.com/getdoc.jsp?containerId=prUS45213219>

Source: Data Fabrics Add Augmented Intelligence to Modernize Your Data Integration, Gartner Group, Dec. 2019

Technology underlies New Healthcare Economy

- ▶ Changing for better of consumer
- ▶ HL7 FHIR for API and digital economy
- ▶ Real-world data and real-world evidence
- ▶ Bridge existing gaps between clinical care and clinical research

Keeping Pace

- ▶ Knowledge, Experience, Life-long Learning

TAKEAWAYS

THANK YOU!

- ▶ Any questions?

- ▶ Contact information

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