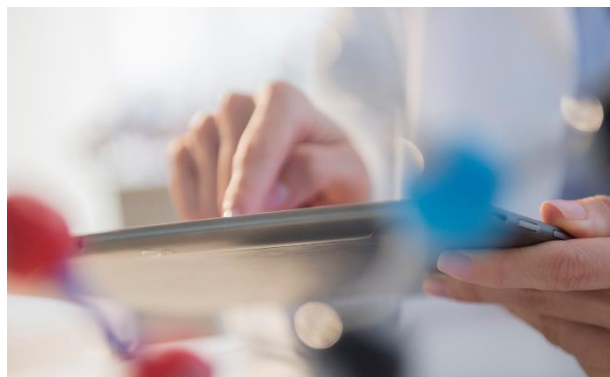
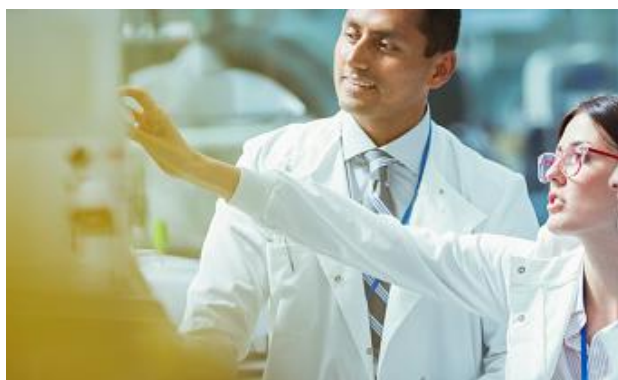




Case Study: Patient Identification in real time



Bariş Erdoğan, PhD
Head of EEMEA Region



Sofia
November 12, 2019



Longevity Ecosystem



Who we are



- A global technology company headquartered in Basel, Switzerland.
- Operating an international hospital network.
- Working in deidentified EHR data since 2012.
- Leveraging real-time, real-patient, and real-world data for clinical research and real-world evidence.
- Working with Top 10 CROs and Top 10 pharma companies.



swiss made
software

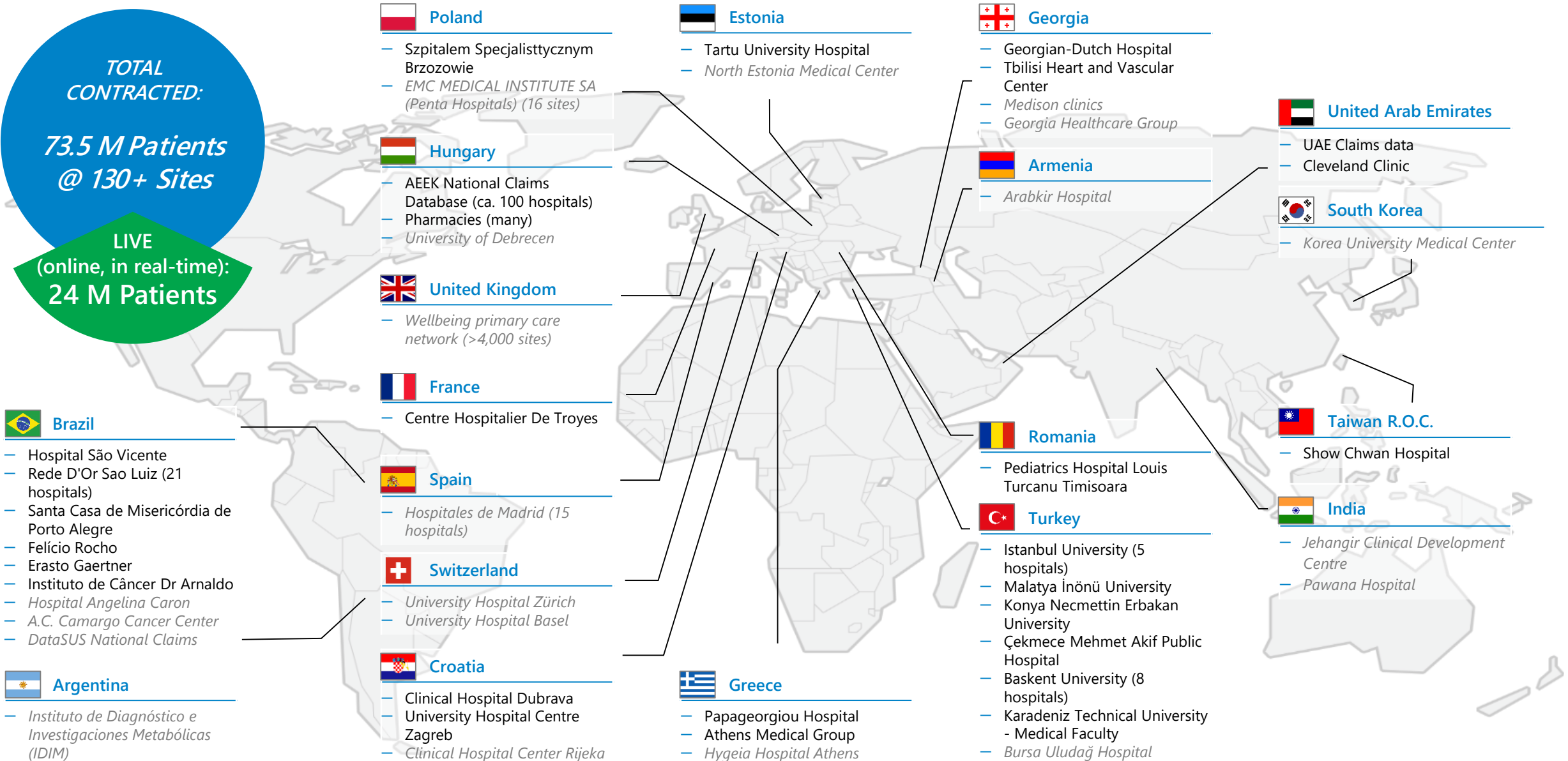


Global Data Coverage

**TOTAL
CONTRACTED:**

**73.5 M Patients
@ 130+ Sites**

**LIVE
(online, in real-time):
24 M Patients**



Today's Clinical Trials – Industry Benchmarks



20%

of sites don't enroll any patients¹



80%

of trials are delayed³



50%+

More than half suffer a protocol amendment²

To improve these you need a new data-driven approach.

¹ Impact Report (2013) Tufts CSDD 15(1)

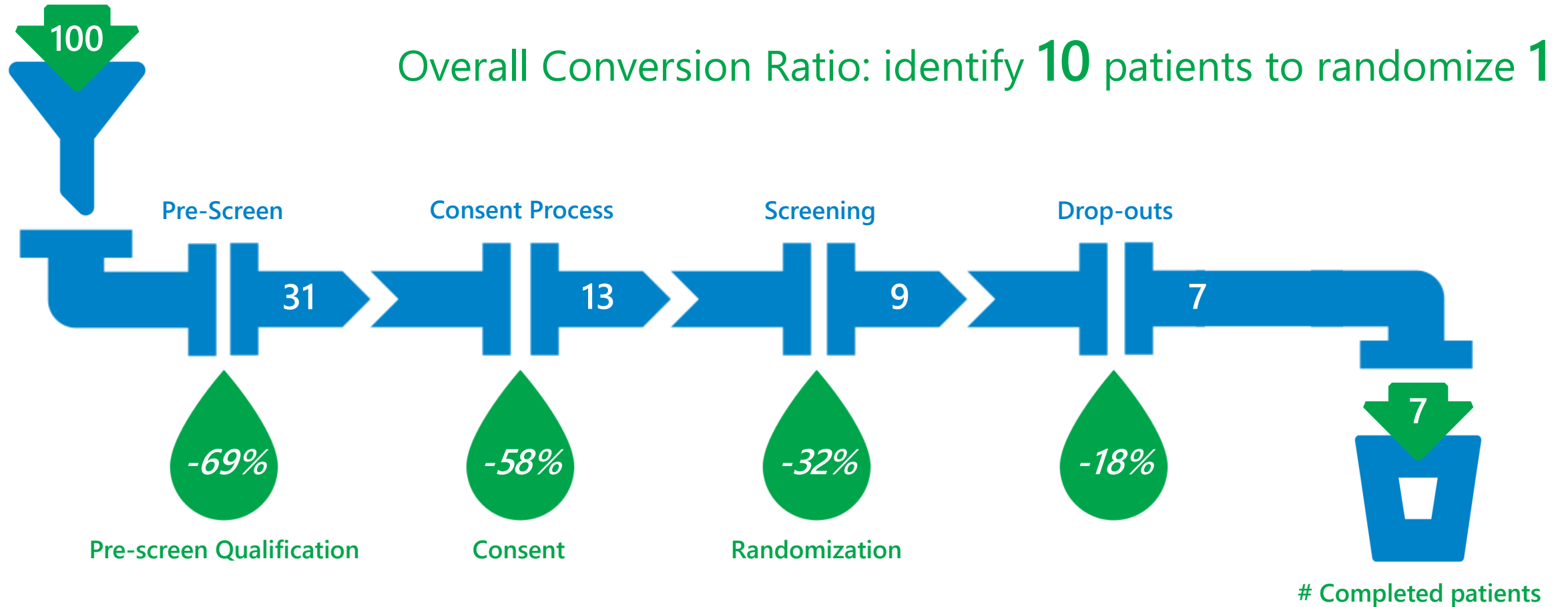
³ Clinical Trial Delays: America's Patient Recruitment Dilemma (2012). Drugdevelopment-technology.com

² Impact Report (2016) Tufts CSDD 18(1).

The Typical Industry Funnel

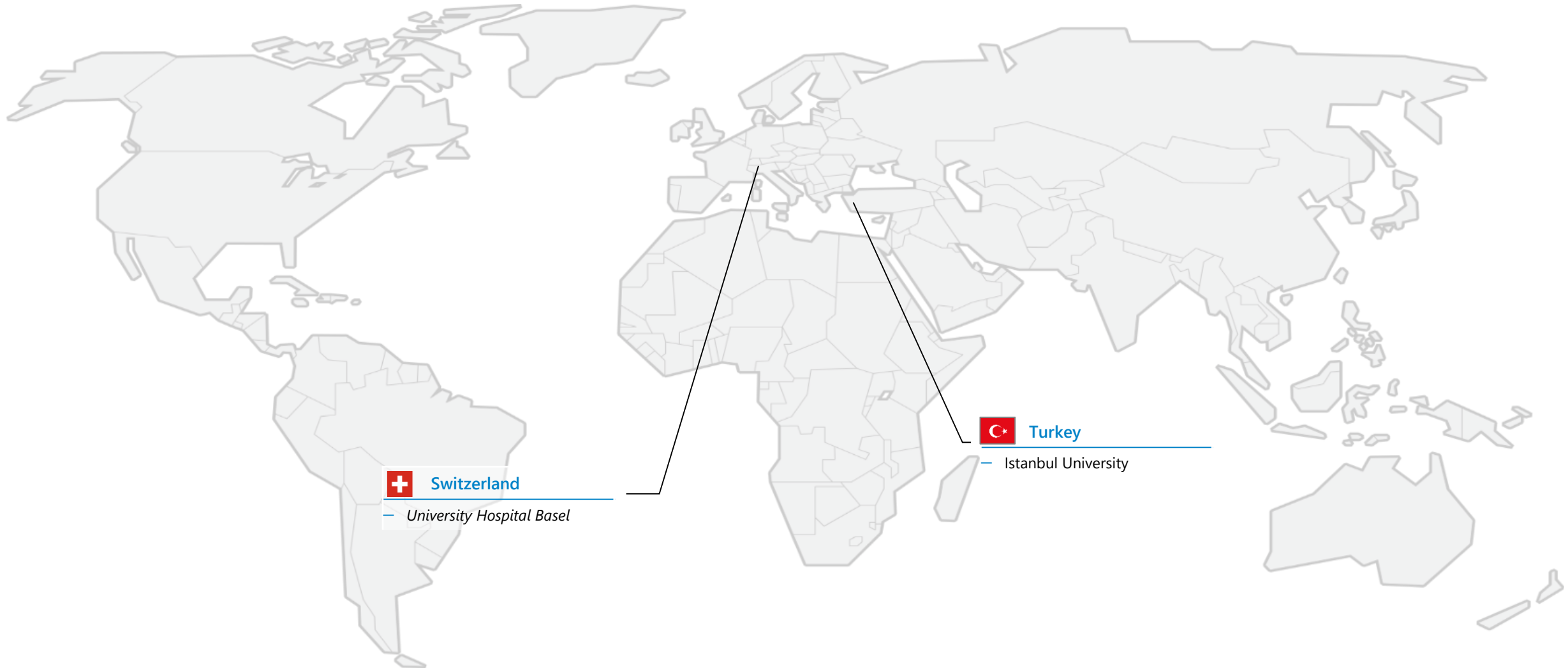
Average Industry Benchmark Data

Patients identified
or available



Benchmark Data – CPP and PhESi-1998-2012

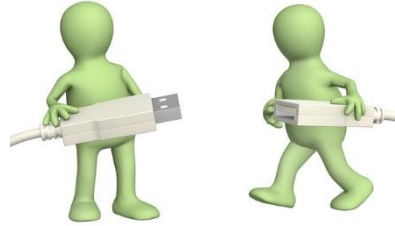
Data Coverage - 2012



Data Flow within Hospital



Data Security,
Privacy & Ethics



Interoperability



Scalability &
Sustainability

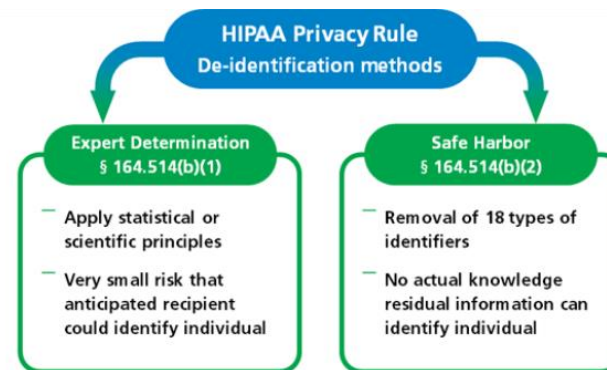


Data Quality

Principles

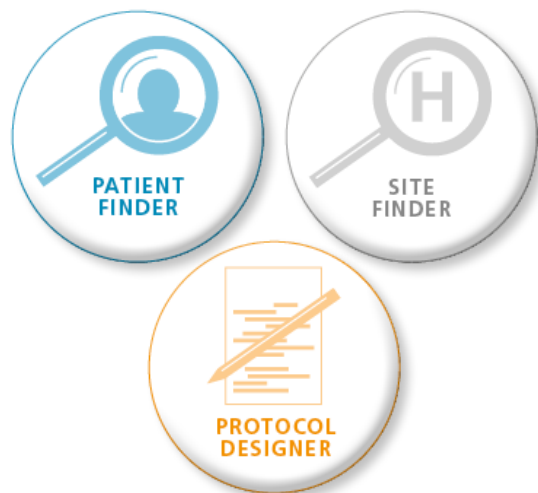
Of *paramount* importance as the value of what we offer is based on patient data.

- We have to be committed to the responsible and trustworthy re-use of health data for research.
- We have to develop systems following “Privacy by Design” principle.
- We must follow international standards, e.g. the US Health Insurance Portability and Accountability Act (HIPAA) and the European General Data Protection Regulation (GDPR) (EU 2016/679).



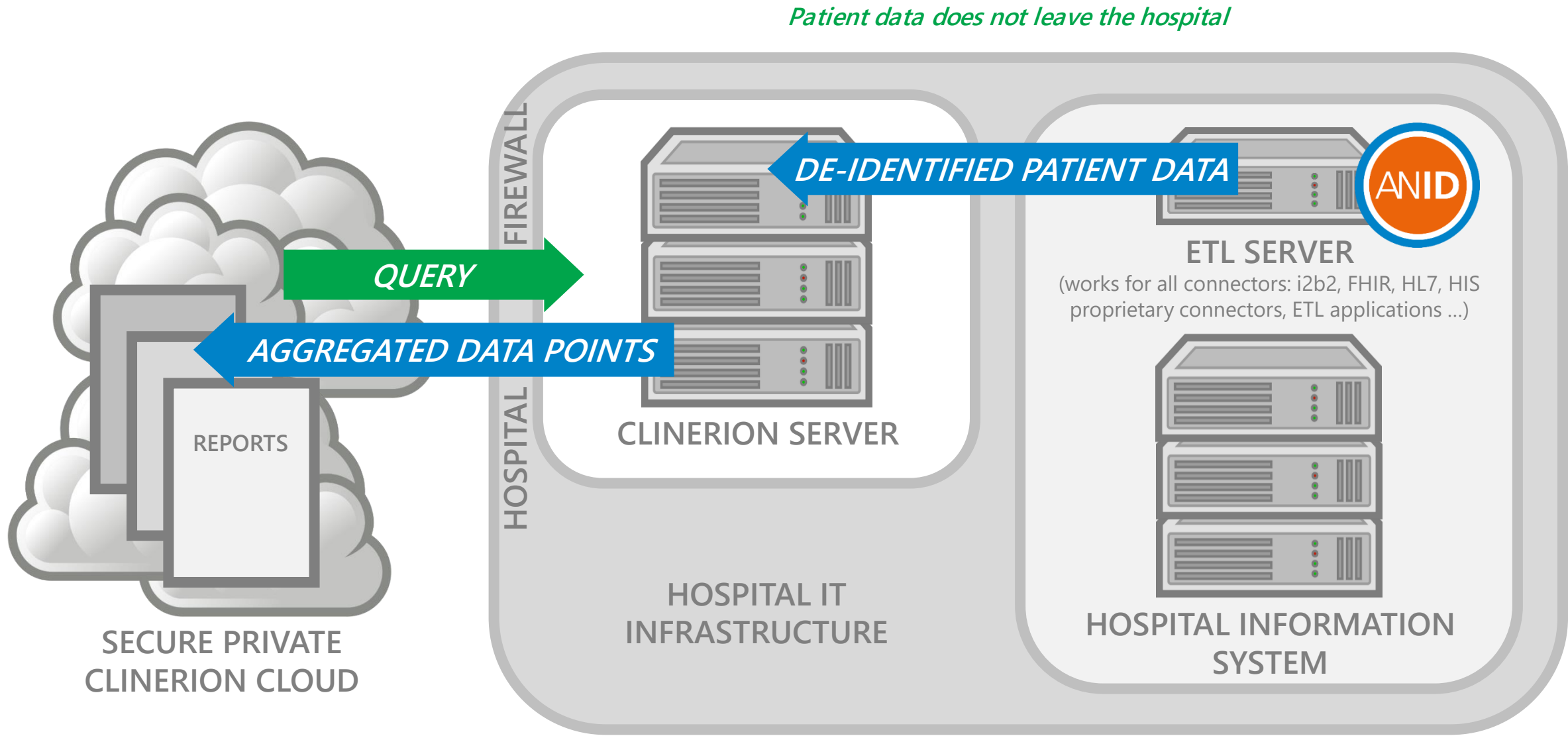
- *NOTE: We should only process anonymized patient data, and anonymized patient data in itself does not fall under GDPR, nor HIPAA.*

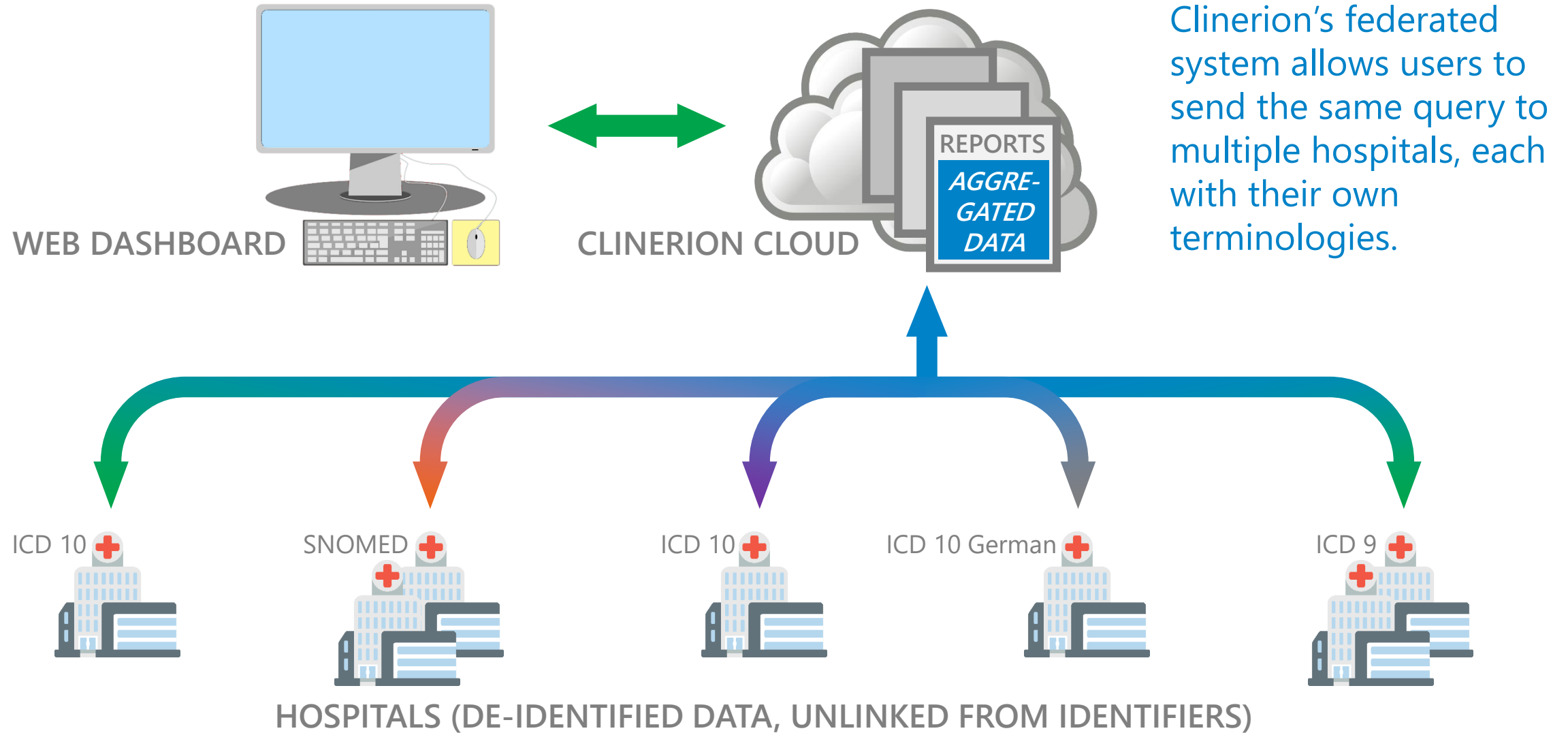
Patient Network Explorer



- Interoperability with multiple systems
 - Legacy and homegrown systems
 - Stand-alone systems
 - Cloud-based 3rd party data systems
- Capability to deliver real-time and historical information
 - Current medications, historical medications
 - Current vitals, health status, notes
 - Longitudinal disease progression for chronic diseases
- Ontology management to map different coding sets of countries/Hospitals
- Implementation difficulties; priorities, system changes, management changes, gap between management and clinical staff
- Server Procurement/Maintenance/Customs Clearance

Data Flow within Hospital





U.S. Department of Health and Human Services

FDA U.S. FOOD & DRUG
ADMINISTRATION

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News & Events

Home > News & Events > Newsroom > FDA In Brief

FDA In Brief

FDA issues policy to facilitate the use of electronic health record data in clinical investigations

f SHARE t TWEET in LINKEDIN p PIN IT e EMAIL p PRINT

July 18, 2018

Media Inquiries

✉ [Stephanie Caccamo](#)
☎ 301-348-1956

“The FDA is committed to developing policies and tools to help researchers access and use data collected from all sources to find ways to improve the safety and efficacy of medical products. This includes ways to expand our methodological repertoire to build on our understanding of medical products throughout their lifecycle – for example, every day health care professionals are updating patients’ electronic health records with clinical outcomes resulting from medical interventions used in clinical practice,” said Jacqueline Corrigan-Curay, M.D., J.D., Director of the Office of Medical Policy in FDA’s Center for Drug Evaluation and Research. “As our experience with new medical products evolves, our knowledge about how to best maximize their benefits and reduce their potential risks sharpens with each data point we gather. Even a single product produces data that can help better inform us about its safety and efficacy. This guidance issued today facilitates the use of electronic health record data in clinical investigations and helps integrate data collected in routine care settings into clinical trials. Harness

Use of Electronic Health Record Data in Clinical Investigations

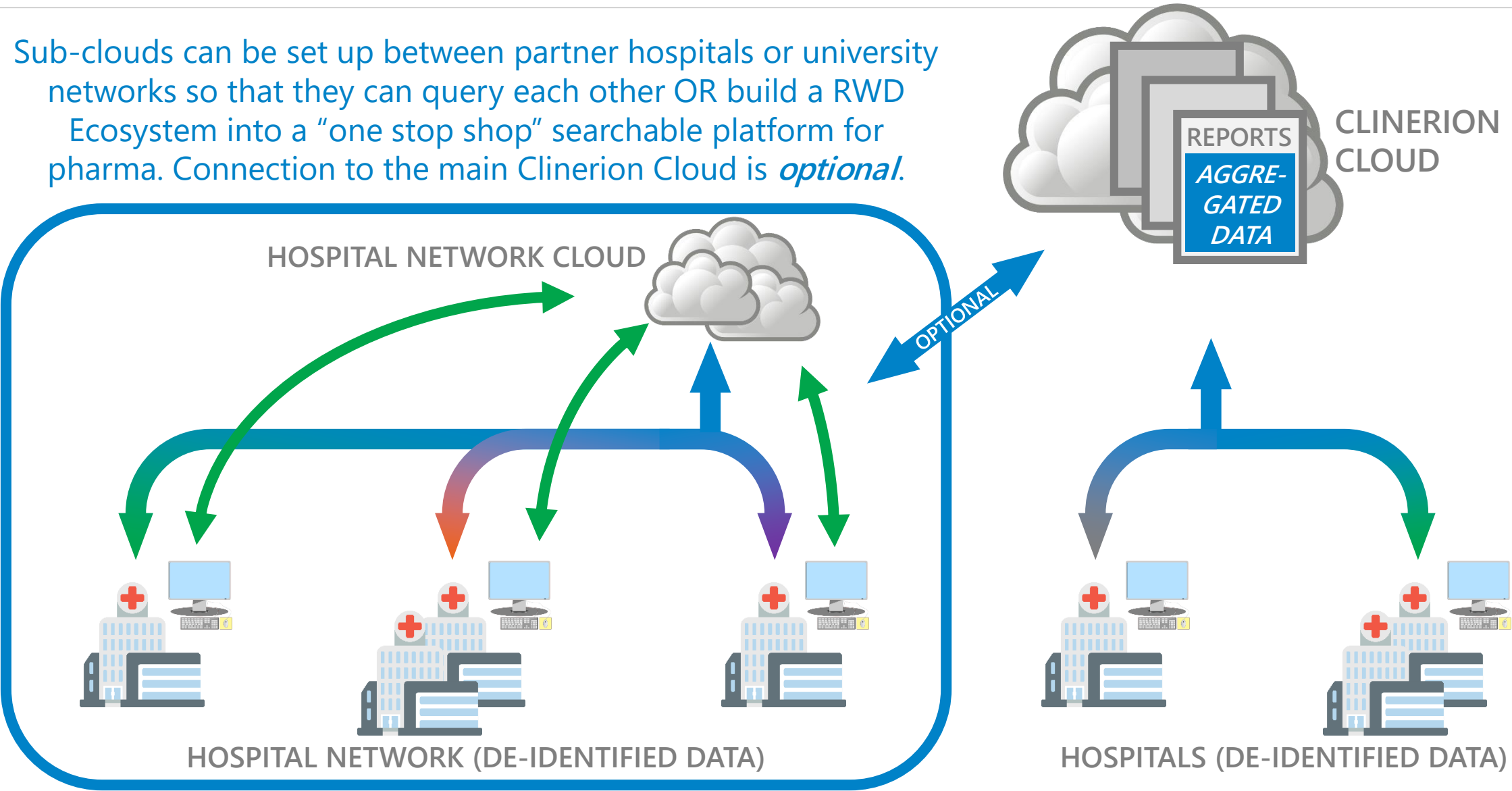
Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)

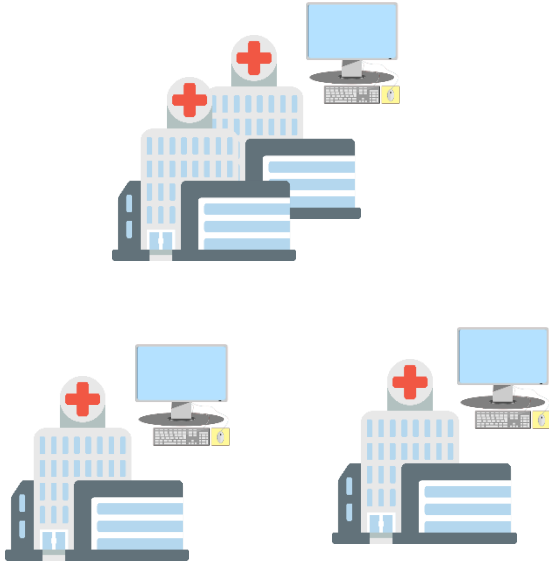
July 2018
Procedural

Patient Network Explorer RWD Ecosystem Build

Sub-clouds can be set up between partner hospitals or university networks so that they can query each other OR build a RWD Ecosystem into a “one stop shop” searchable platform for pharma. Connection to the main Clinerion Cloud is *optional*.



Research Network



- the network may access a larger pool of patients
- access to experts in a variety of fields and to facilities offering other treatment methodologies
- not every hospital's research department is funded well enough to be able to afford state-of-the-art equipment
- not every research institute has access to experts in every field required by the research topic
- resources and costs may be shared
- IT infrastructure solutions may also be shared

Contains Nonbinding Recommendations

Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on August 31, 2017.

The draft of this document was issued on July 27, 2016

For questions about this document regarding CDRH-regulated devices, contact the Office of

(2) Data assurance - Quality Control

Data quality control is essential for providing confidence in the reliability of RWD and RWE sources. RWD quality can generally be improved by following published recommendations concerning registries, such as those by the Agency for Health Care Quality, Patient-Centered Outcomes Research Institute,²² the National Medical Device Registry Task Force,²³ and the Regulators Forum (IMDRF) Registry Working Group.²⁴ However, certain sources of RWD, such as some administrative and healthcare claims databases or EHRs, may not have established data quality control processes and may not be capable of fully implementing or following the above recommendations. When considering a source of RWD for regulatory purposes, it is important to consider any methods and systems used to help ensure sufficient data quality. Potential RWD sources should be evaluated in accordance with the data QA plan and procedures developed for the data source itself. Since evaluation of RWD sources may not always permit specific line item source verification, important factors for consideration include:

- the quality of data element population (e.g., whether abstracted from a verifiable source to assess transcription errors or automatically populated through a data extraction algorithm);
- adherence to source verification procedures and data collection and recording procedures for completeness and consistency;
- completeness (i.e., minimized missing or out of range values) of data necessary for specified analyses, including adjustment for confounding factors;
- data consistency across sites and over time;²⁵



T.C. SAĞLIK BAKANLIĞI
Sağlık Hizmetleri Genel Müdürlüğü

MÜSTEŞAR - SAĞLIK HİZMETLERİ GENEL MÜDÜRLÜĞÜ
22.04.2017 16:18 - 64047795-010 06.01-213
00045705341

Sayı : 26325996
Konu : Klinik Kalite Uygulama ve Veri Kalitesi İyileştirme Rehberi

GENELGE
2017/- 8

Bakanlığımızca Sağlıkta Dönüşüm Programı ile birlikte nitelikli ve etkili sağlık hizmeti için kalite ve akreditasyon faaliyetlerine başlanmış ve ülke genelinde bu alanda önemli bir mesafe kat edilmiştir. Bu kapsamda kalite ve akreditasyon faaliyetleri bünyesinde, teşhis tedavi ve bakım süreçlerinin iyileştirilmesi amacıyla Türkiye Klinik Kalite Ölçme ve Değerlendirme Sistemi'nin kurulmasına yönelik çalışmalar başlatılmıştır.

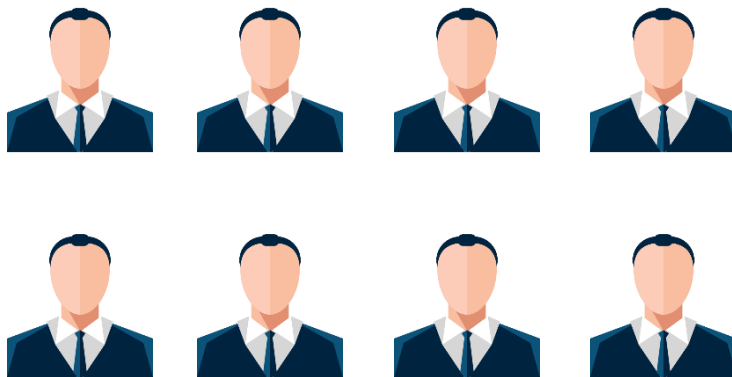
Sistem, hastalık yükü, ölçülebilirlik ve süreçlere müdahale ile iyileştirmeye açık olma özelliği dikkate alınarak, belirlenen sağlık olgularına yönelik tıbbi süreçler ve klinik sonuçların kurumsal, bölgesel ve ulusal düzeyde izlenmesi, analiz edilmesi ve iyileştirilmesini amaçlamaktadır. Sistem kapsamında sağlık olgusu ve göstergeler belirlenmiş, söz konusu göstergelere ilişkin verilerin elde edilmesi amacıyla E-Nabız üzerinde Klinik Kalite Karar Destek Sistemi oluşturulmuştur.

Gösterge sonuçlarına yönelik analizlerin doğru yapılması ve iyileştirmeye açık alanların doğru şekilde belirlenmesi için sistemden doğru verilerin elde edilmesi büyük önem arz etmektedir. Bu bağlamda, takip edilen sağlık olgularına dair klinik süreçlerin kalitesi ile ilgili sorumlu ve sorumlulukların tanımlanması, elde edilen verilerin doğrulanması ve veri kalitesinin iyileştirilmesine yönelik sağlık kuruluşlarında gerçekleştirilmesi gereken faaliyetlere ilişkin "Klinik Kalite Uygulama ve Veri Kalitesi İyileştirme Rehberi" hazırlanmıştır. İlgili rehber <http://kalite.saglik.gov.tr/> adresinden ulaşılabilmektedir.

- Data Manager
- Data Analyst
- Data Quality Officer

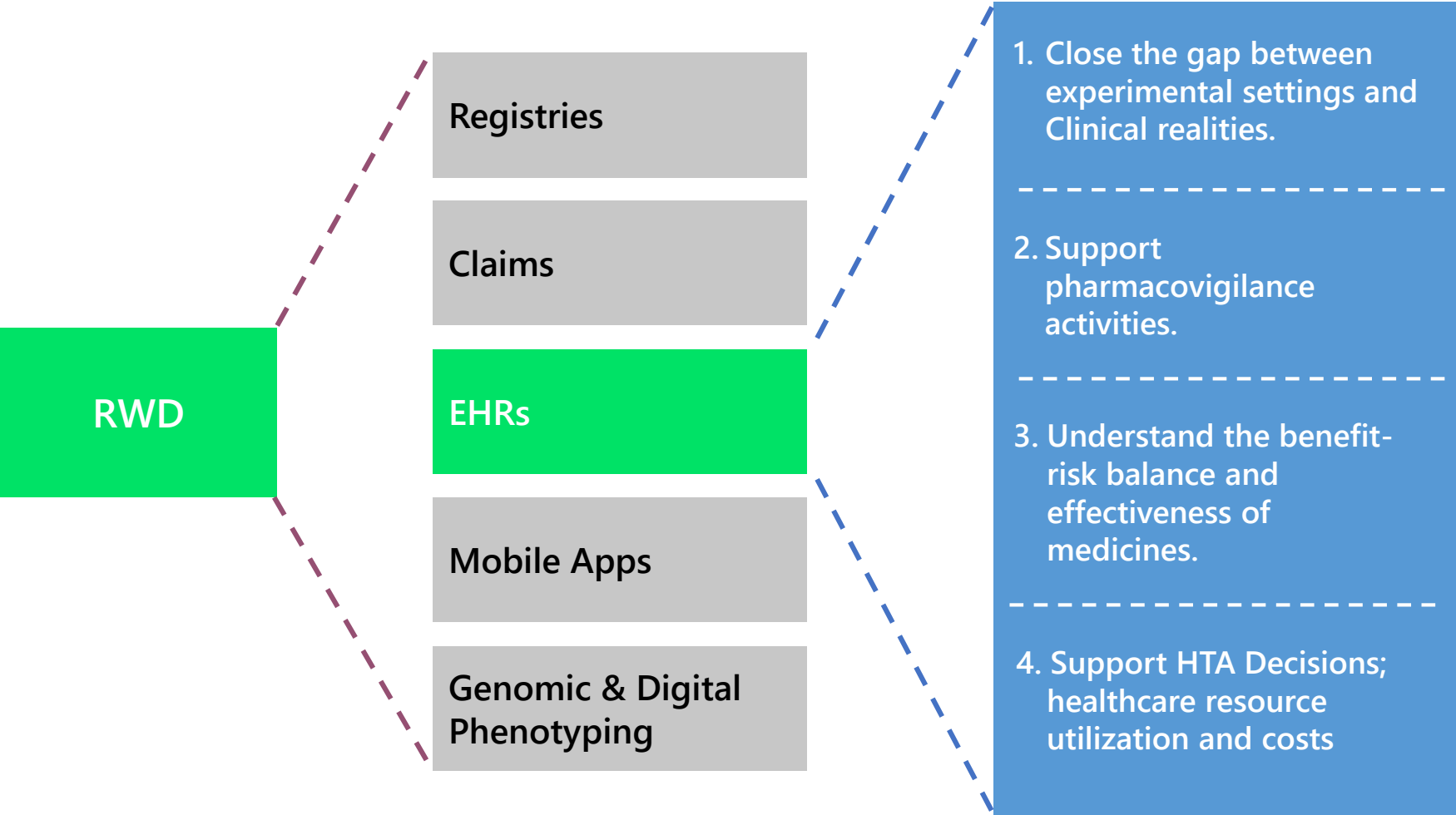
RCT – RWD Difference

RCT: They excel at answering scientific questions about how well a treatment works and its potential side effects in controlled conditions with specific inclusion/exclusion criteria.



RWD: Real-world patients may be older, have different ethnicity, have more medical conditions, and have more advanced diseases.





Real-World Evidence Applications



You give us your questions, we give you real-world answers



Late phase studies. Prospective and retrospective.

Post-marketing surveillance – monitor efficacy, safety and personalized outcomes.

Prevalence queries and patient journey analysis



Ensures that all patients who could benefit get access to a drug at the right price.

Planning of how the drug fits into the market.

RWE Support Across The Product Lifecycle

Target Selection

- Understand unmet medical needs
 - How large is the patient population
 - How are they treated
 - Outcome / risk?
 - Which are the high risk groups?
 - What is the cost of treating/not treating them?

Launch

- Interpretation of trial results.
 - Who would benefit most from the treatment?
- Preparation of reimbursement and regulatory dossiers
- RWE insight into product go/no go decisions

Commercialization

- RWE insights to support reimbursement and market access.
- RWE comparative effectiveness evidence relative to competitors.
- Long-term safety and effectiveness evidence
 - Who are treated? For how long?
 - Switch pattern?

Treatment Pattern

- Which drug should be given first?
- What's the best combination?
- Analysis of index or event driven scenarios

Disease Burden

- What is the incidence/prevalence of a disease?
- What is the cost of treatment?
- What is the morbidity and death rate of the disease?

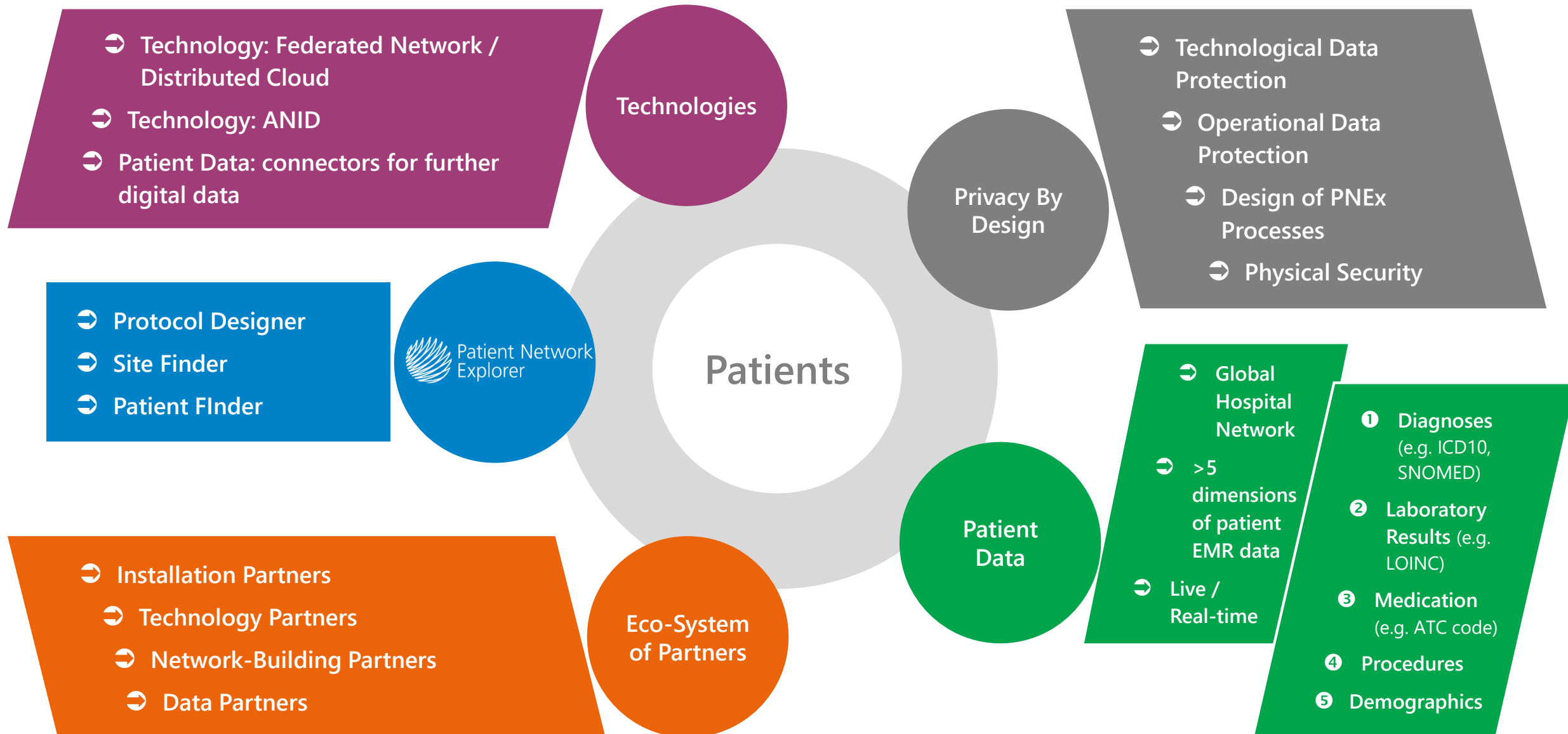
Patient Adherence to Therapies

- What happens in real-life outside of RCTs?
- What happens if the patient drops treatment?

Analytics Based on a Specific Timepoint

- Predicted length of stay for a person with a pre-existing condition A and a person in normal health plotted against a particular laboratory result X.

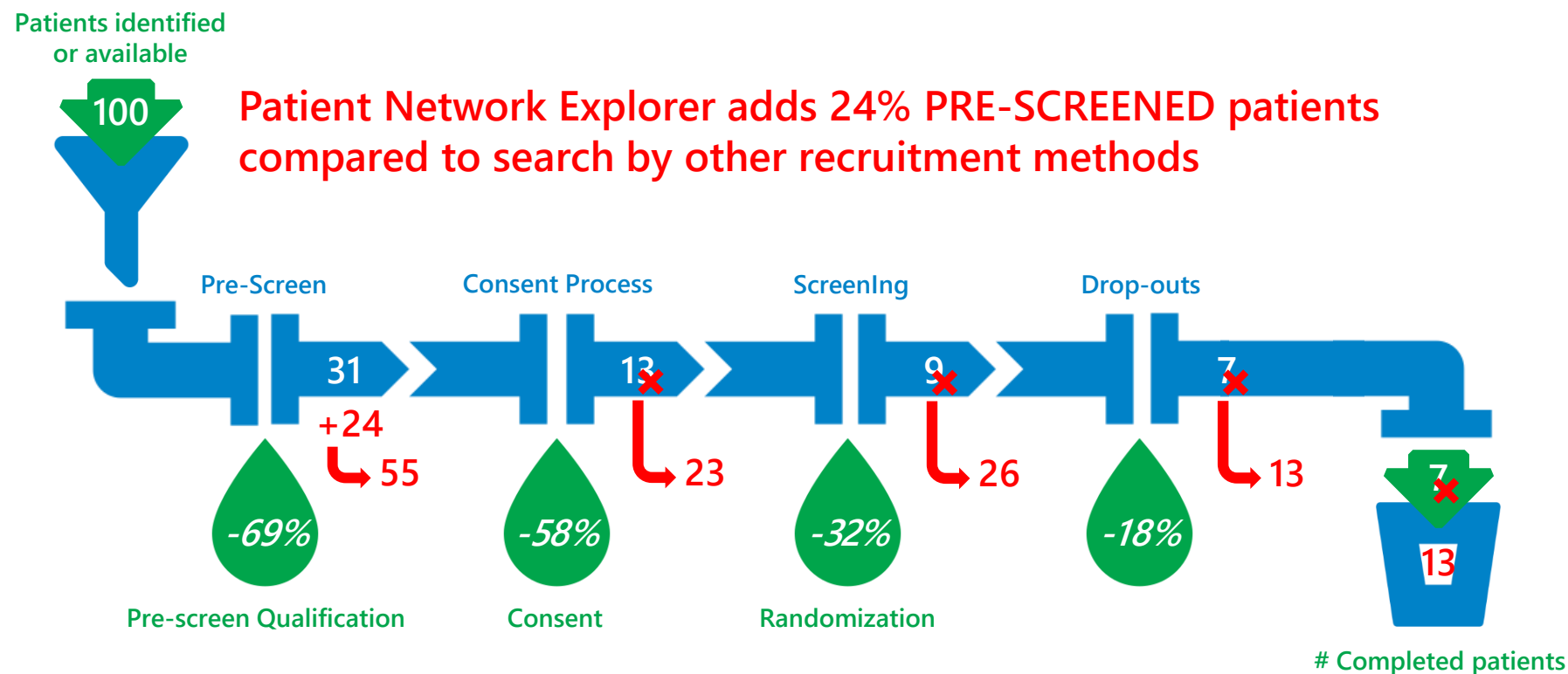
What Clinerion Has



Case Study – Hospital São Vicente de Paulo 4

Run by
Bioserv SMO

Comparison vs Average Industry Benchmark Data



Value Proposition in the Development Cycle – *Re-imagining Research*



Thank you



www.clinerion.com

Baris.Erdogan@clinerion.com

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