

SANOFI DIGITAL INITIATIVES AND POTENTIAL IMPACT ON THE DATA MANAGEMENT

DMB Paris, November 14th 2017

Fabien DIDIER - SANOFI : DM Experts Cluster Lead



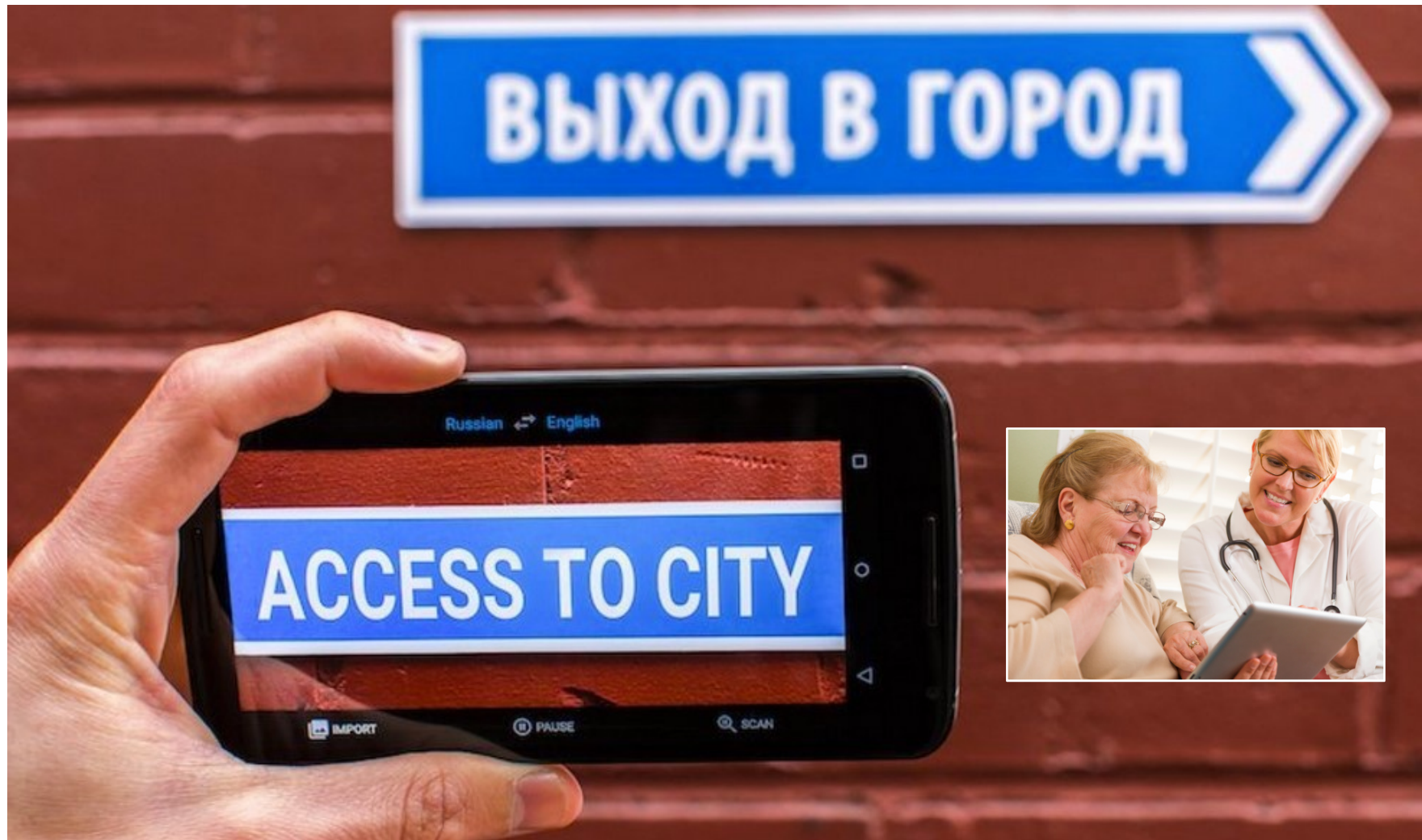
AGENDA

- Introduction
- Some of the Sanofi Digital Initiatives
- Summary of the potential impact on the Data management

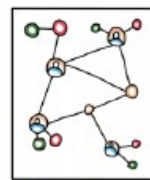
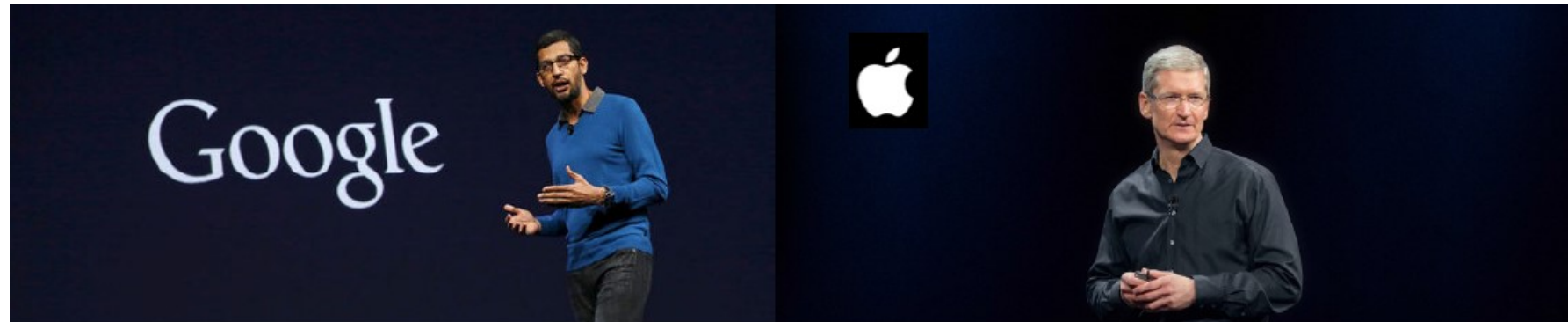
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TECHNOLOGIES THAT MEET END USER NEEDS GENERATE
OUTCOMES THAT MATTER TO PEOPLE



CONNECTIVITY OFFERS MULTIPLE OPPORTUNITIES TO GENERATE AND PROCESS PEOPLE EXPERIENCE DATA



Social Media



Mobile

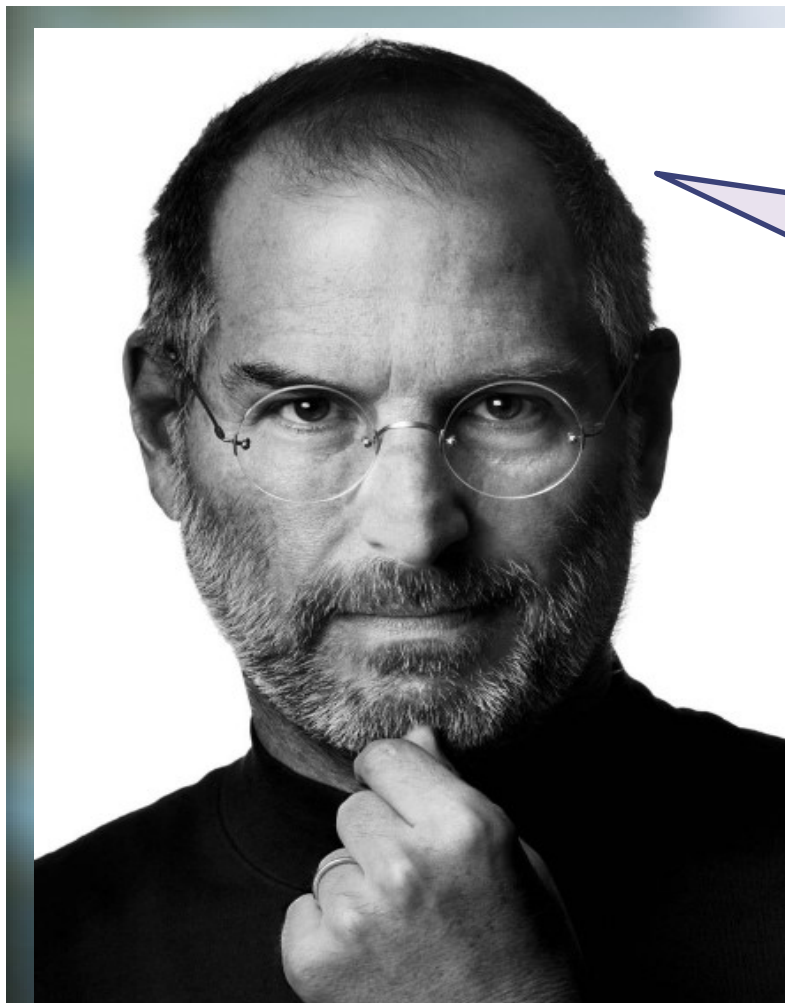


Wearables



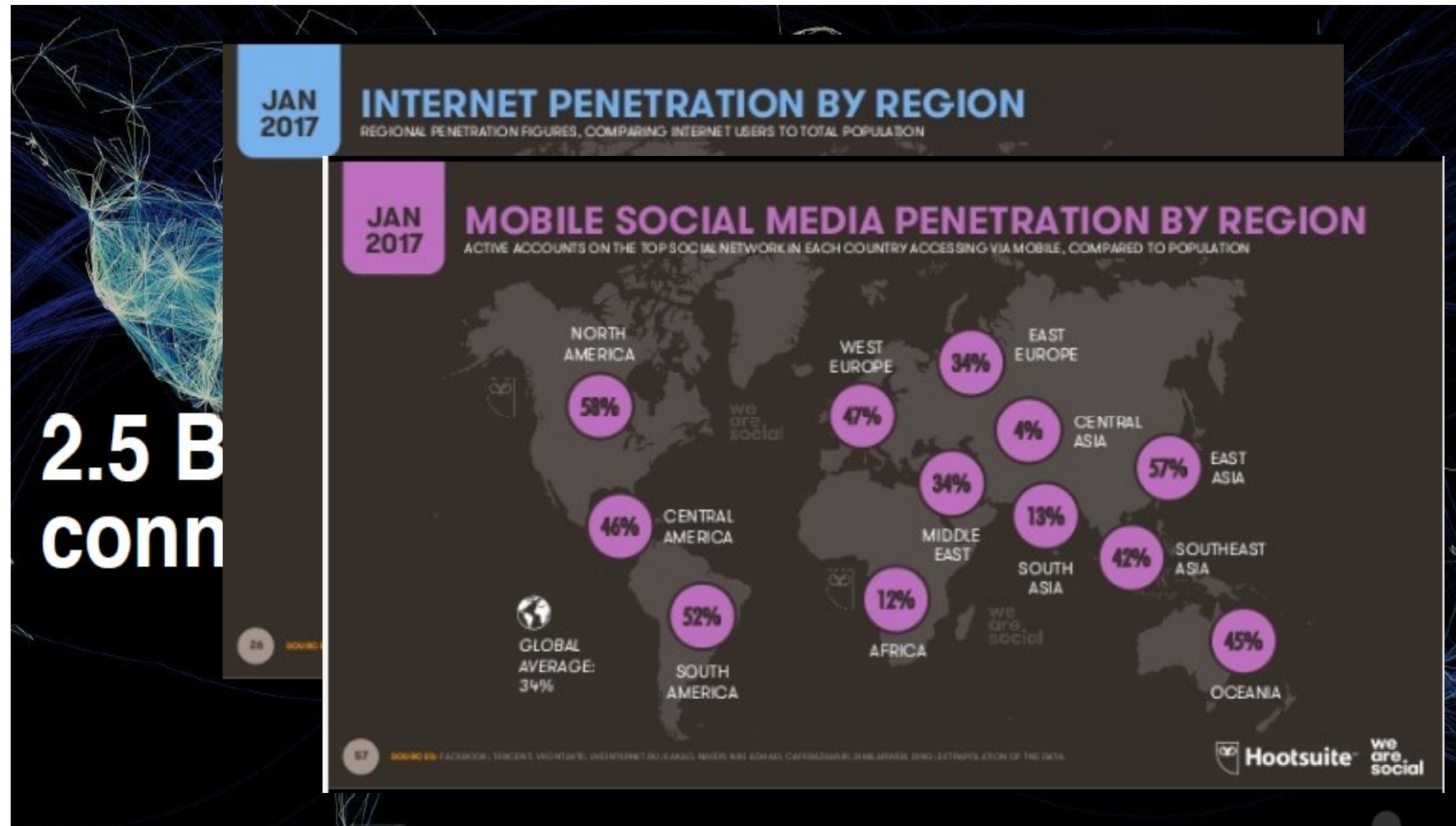
Big Data





“the biggest innovations of
the 21st century will be at
the interaction of biology
and technology”

DIGITAL TECHNOLOGY EMPOWERS PEOPLE IN AN INCREASINGLY CONNECTED WORLD



SOME KEY MESSAGES FROM THE SANOFI TOP MANAGERS

It took 75 years for the telephone to reach a hundred million users, it took the iPhone four.

It took Facebook four & a half years to reach 100 million users, Pokemon GO reached that many people in three short weeks.

DIGITAL JUST SPEEDS THINGS UP.

For a long time, the pharma industry has been a slow adopter of digital, now we are actively working to speed up & improve our healthcare delivery to patients.

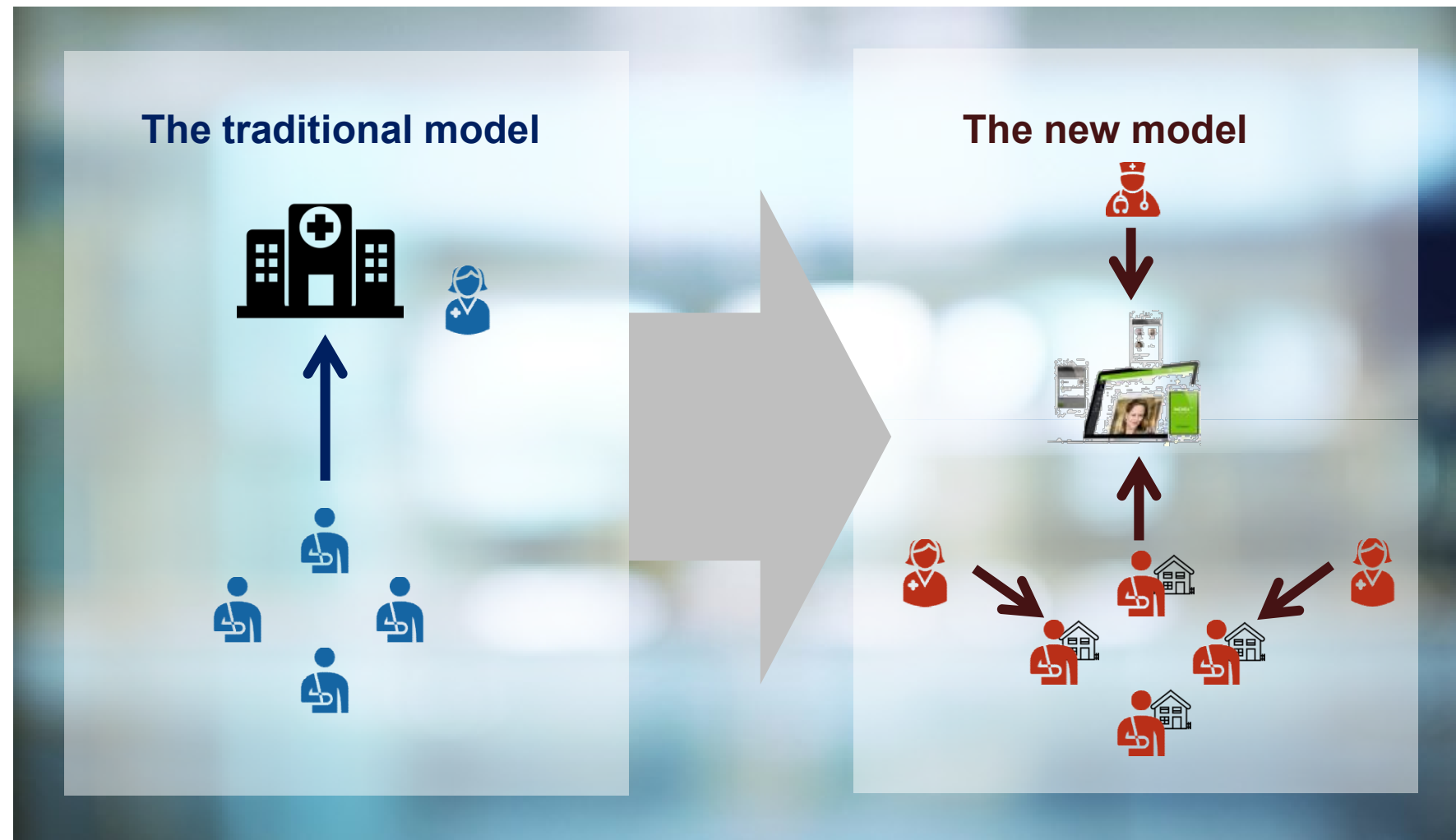
Digital connects people, and it connects people at really low cost.

The patient never has to go to the hospital

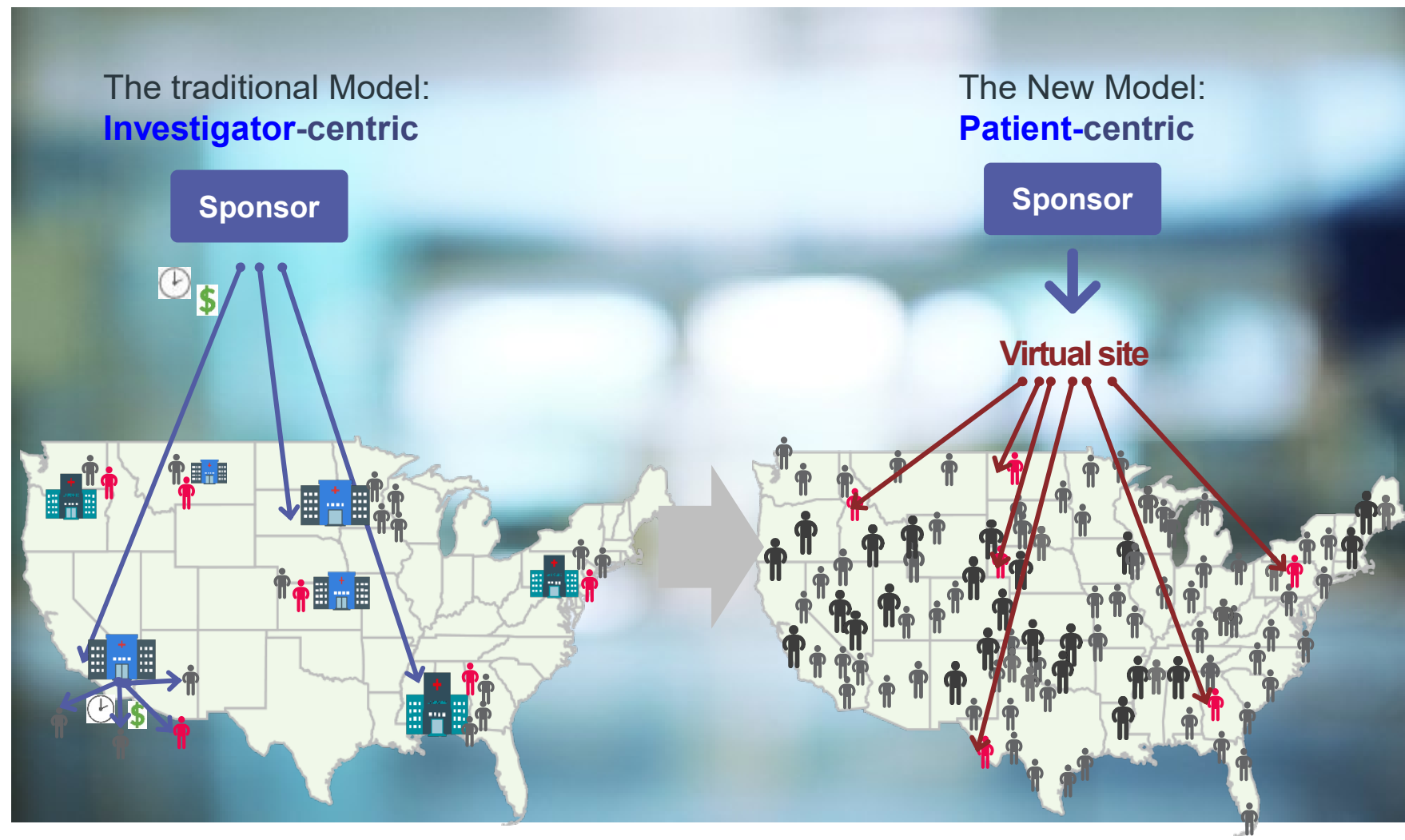
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DISTRIBUTED STUDIES ARE OPENING NEW POSSIBILITIES IN CLINICAL TRIAL DESIGN



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REMOTE, TECHNOLOGY-ENABLED TRIAL DESIGN IS INCLUSIVE TO POPULATIONS WE COULD NOT EASILY REACH SO FAR



DISTRIBUTED STUDIES & DATA MANAGEMENT IMPACT



EXPECTED BENEFITS:

- ✓ More patient in less time. Make trials feasible to study rare disease and cancer with specific mutations
- ✓ Potential better retention due to lower burden and/or better data quality
- ✓ Potential saving

DATA MANAGEMENT IMPACT:

- ✓ Complex data flow
- ✓ Data integration
 - ✓ In or out the EDC
- ✓ More vendors to manage
 - ✓ “Start up” vendor with low expertise in DM & Clinical trials

The diagram illustrates a shift from a traditional model of education to a new model. A large grey arrow points from left to right, indicating the transition.

The traditional model

This model is represented by a blue funnel. A single blue icon of a person with a headset and network connections is positioned above the funnel, with a blue arrow pointing down into it. Below the funnel, two blue icons of people are shown, representing a limited output.

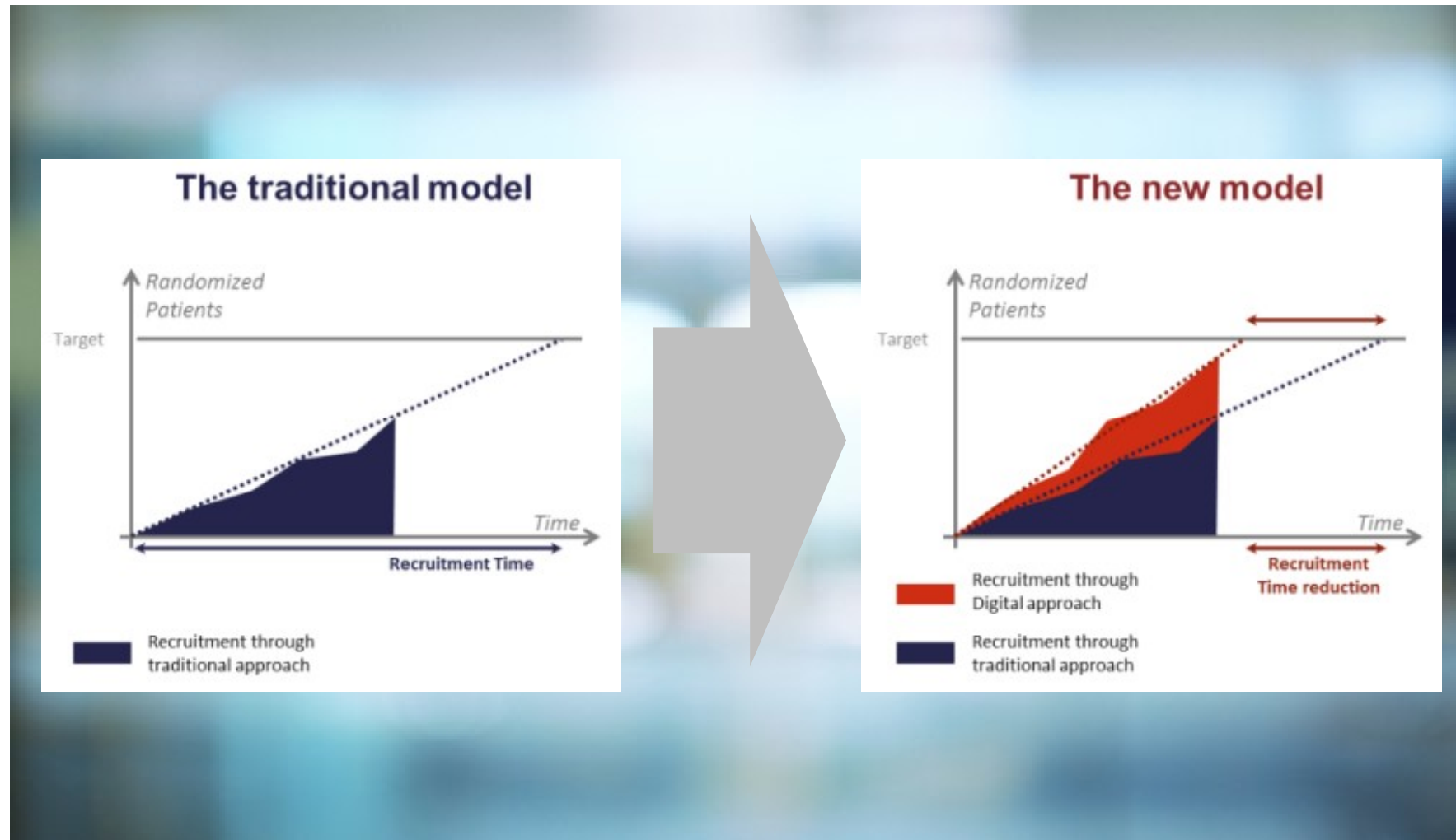
The new model

This model is represented by a red funnel. Above the funnel, four red icons are shown: a web browser window with 'www', a person with a headset, a person with a magnifying glass, and a clipboard with 'A+'. Red arrows point from each of these icons down into the funnel. Below the funnel, five red icons of people are shown, representing a significantly increased and more diverse output.

MULTI-CHANNEL RECRUITMENT COMPLEMENTS OTHER SOURCES OF RECRUITMENT TO REDUCE TIME



TRADITIONAL MODEL VS NEW MODEL



MULTI-CHANNEL RECRUITMENT & DATA MANAGEMENT IMPACT



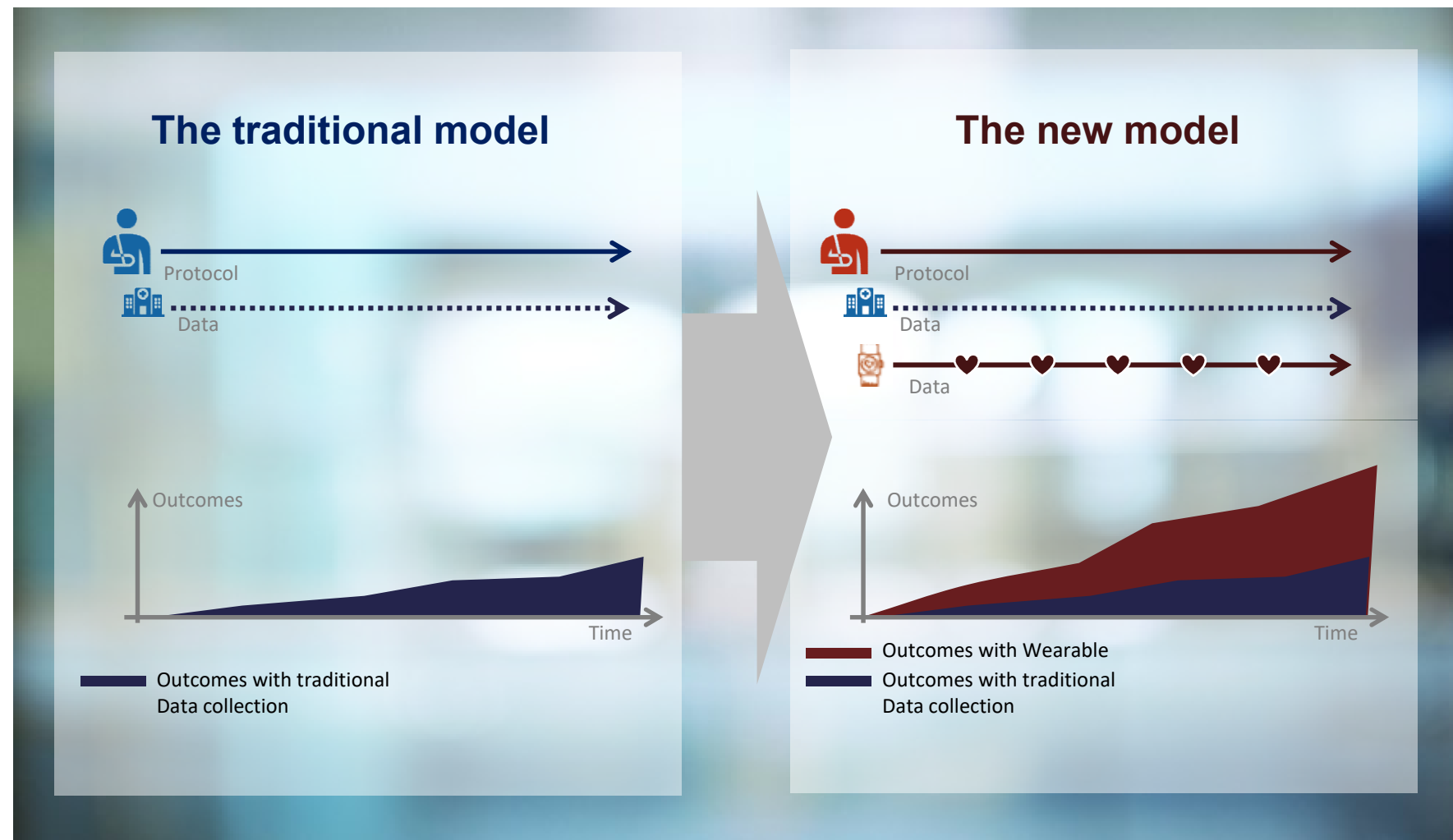
EXPECTED BENEFITS:

- ✓ Potential time savings from avoiding delays to saving several months.

DATA MANAGEMENT IMPACT:

- ✓ Solution to identify the patients coming from the multi channel
 - ✓ To better monitor / Evaluate our MCR Service provider
 - ✓ Financial aspect
 - ✓ Dash- boarding

INTEGRATION OF WEARABLE DEVICES OPTIMIZES DATA CAPTURE AND DISSEMINATION 24/7 DAYS A WEEK



WEARABLE DEVICES



EXPECTED BENEFITS:

- ✓ Capture & collect continuous, accurate health data in real time without extra effort from the patient
- ✓ Gather better data; possibly also fewer clinical visits over time, lowering patient burden, greater patient engagement
- ✓ Evaluate the use of wearables for endpoints

DATA MANAGEMENT IMPACT:

- ✓ Data integration
- ✓ Data reliability
- ✓ Amount of data
- ✓ Data validation

INNOVATIVE MEDECINES INITIATIVE (I.M.I) : EHR2EDC

Context

- The complexity and the cost of CTs
- amount of data to be collected= burden for hospital site staff.
- Need for more Real Word Data
- Recent survey: hospitals perceive that 70-100% of data is duplicated across their EHR and EDC systems.

Project Organization and Timelines

2017: Project Planning

2018: Techno development / Network expansion

2019: Techno validation / Trial initiation (3 studies)

2020: Results publication & generalization planning

The EHR2EDC Project

- Re-use of EHR information within a clinical trial.
- This project led by Sanofi will be co-developed by a consortium of pharma and hospitals.
- This project has 3 pillars:



A new InSite Platform Service to enable direct data capture from EHRs to eCRF



An Education & Training Program for Hospitals Staff, to increase data quality



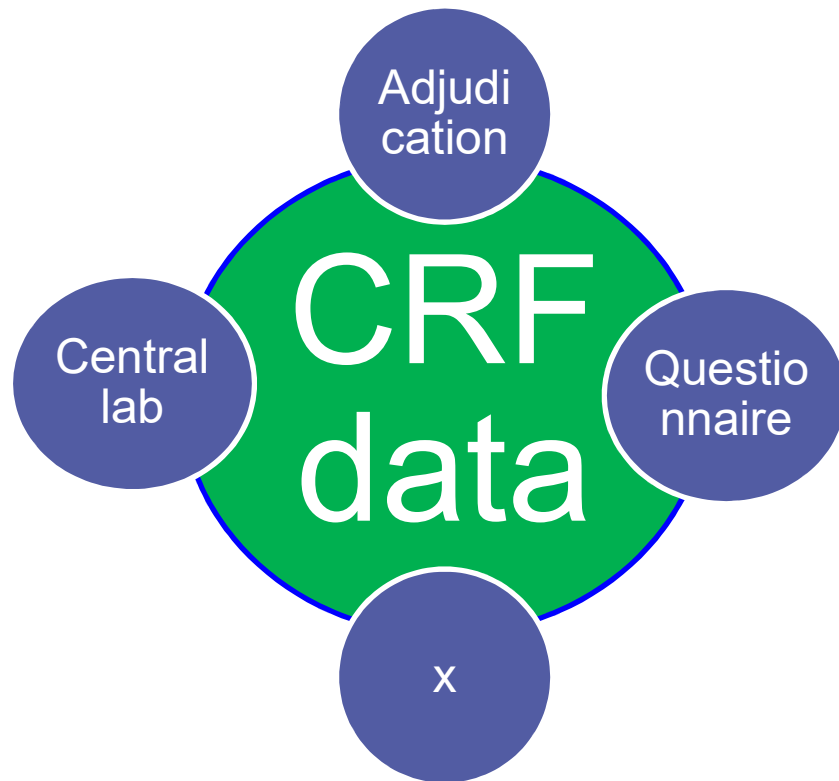
Increase the number of connected Hospitals in Europe and WW to enable RWD driven drug development

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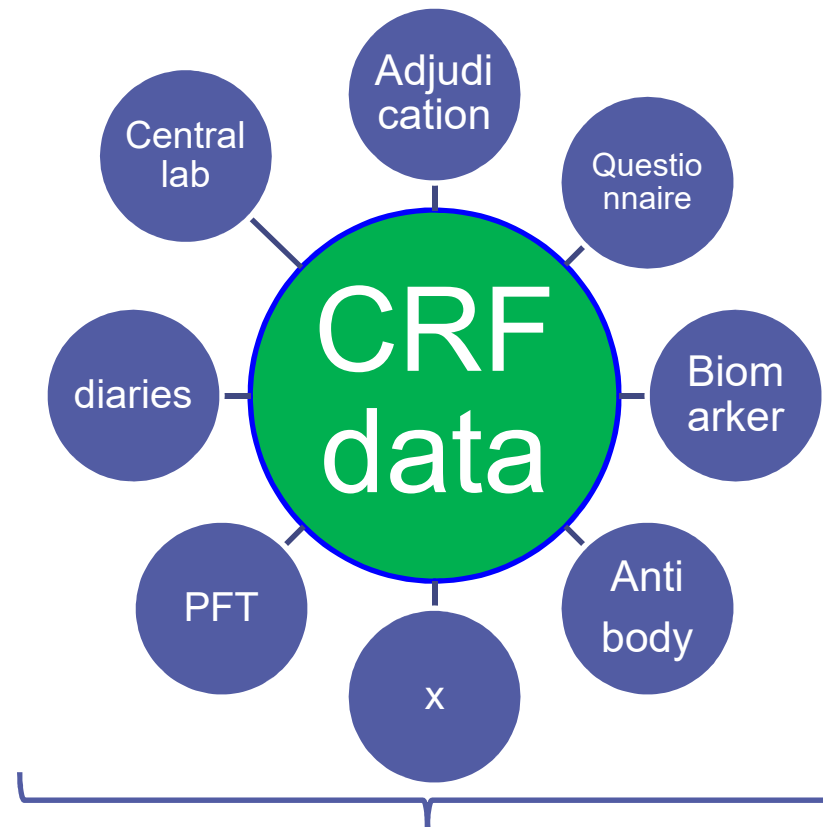
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EVOLUTION OF THE DATA COLLECTION

PAST



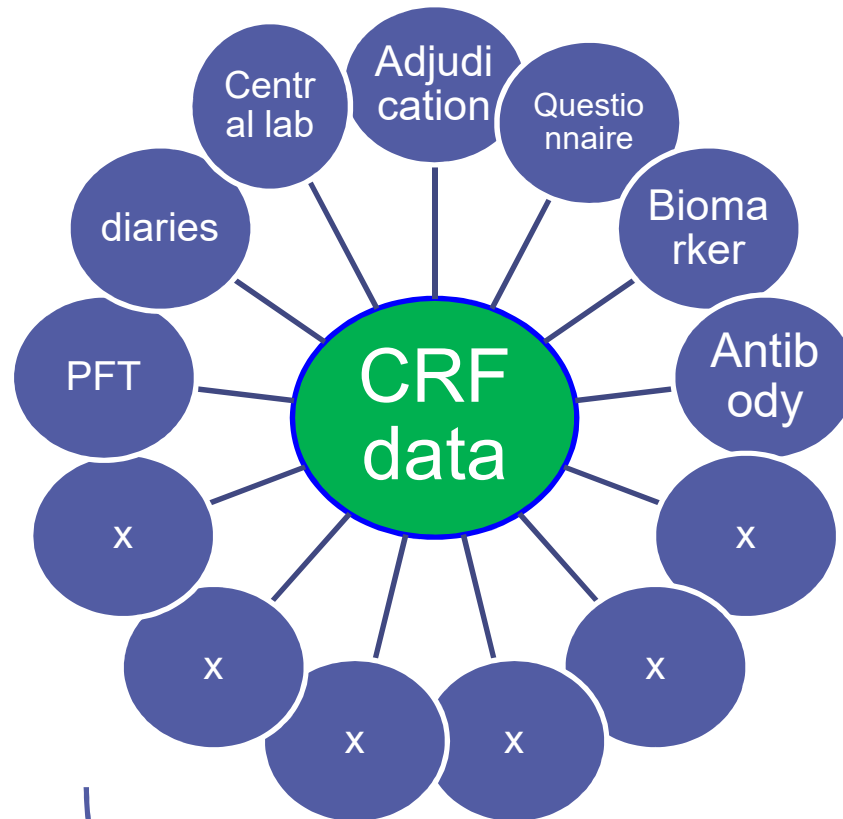
PRESENT



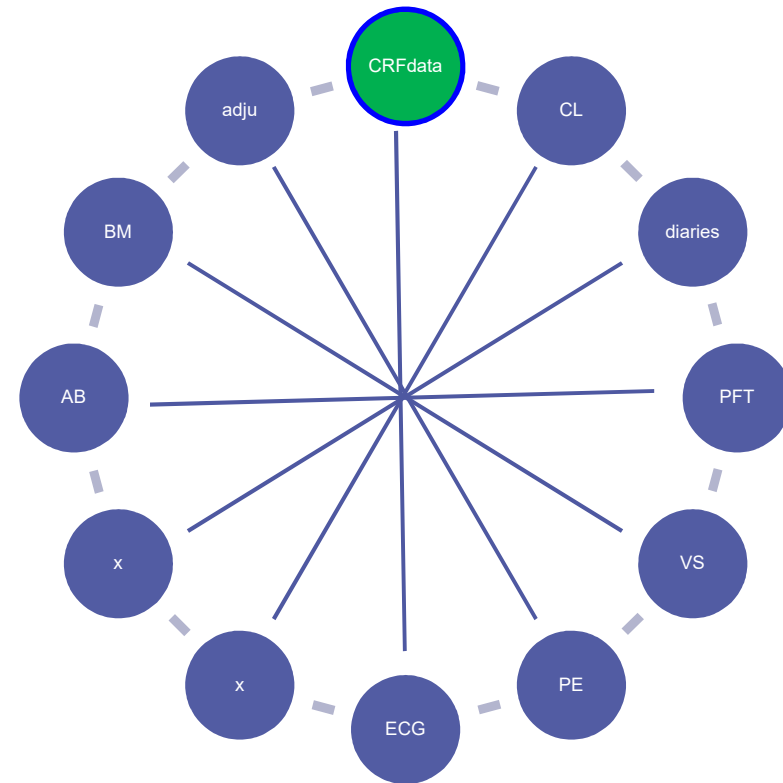
Do we have the appropriate IT landscape ?

EVOLUTION OF THE DATA COLLECTION

FUTURE 1



FUTURE 2



Will we still need an EDC ?

CHALLENGES & CONCLUSION

Data flow
Data integration
Data integration
Data integration

**Data validation strategy: Risk
Based DM approach**

**Vendors selection
& management**

Patient centricity

**Opportunity to deliver new
treatment faster at lower cost**

Anticipate your needs

Build 'good' standards

**Have in mind your complete DM
landscape**

- Have we reached our model limit ?
- What about our EDC added value ?

Real Word Evidence

Return On Investment

BACK UP SLIDES



Wait, wait. What about regulation?

Yes.

We operate in a heavily regulated environment, and need to be careful not to break any laws or regulations.

But.

“The startups – the disruptors – won’t care about regulation. They will find a way” – *Sanofi leadership members*

- Shaped the regulatory environment
- Acted first, then asked for approval
- \$70B+ valuation after 5 years



- Waited for government help / protection-ism
- -50-+% value of medallion – from \$670K to ~\$200K in Boston

