SANOFI DIGITAL INITIATIVES AND POTENTIAL IMPACT ON THE DATA MANAGEMENT

DMB Paris, November 14th 2017

Fabien DIDIER - SANOFI : DM Experts Cluster Lead

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AGENDA

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

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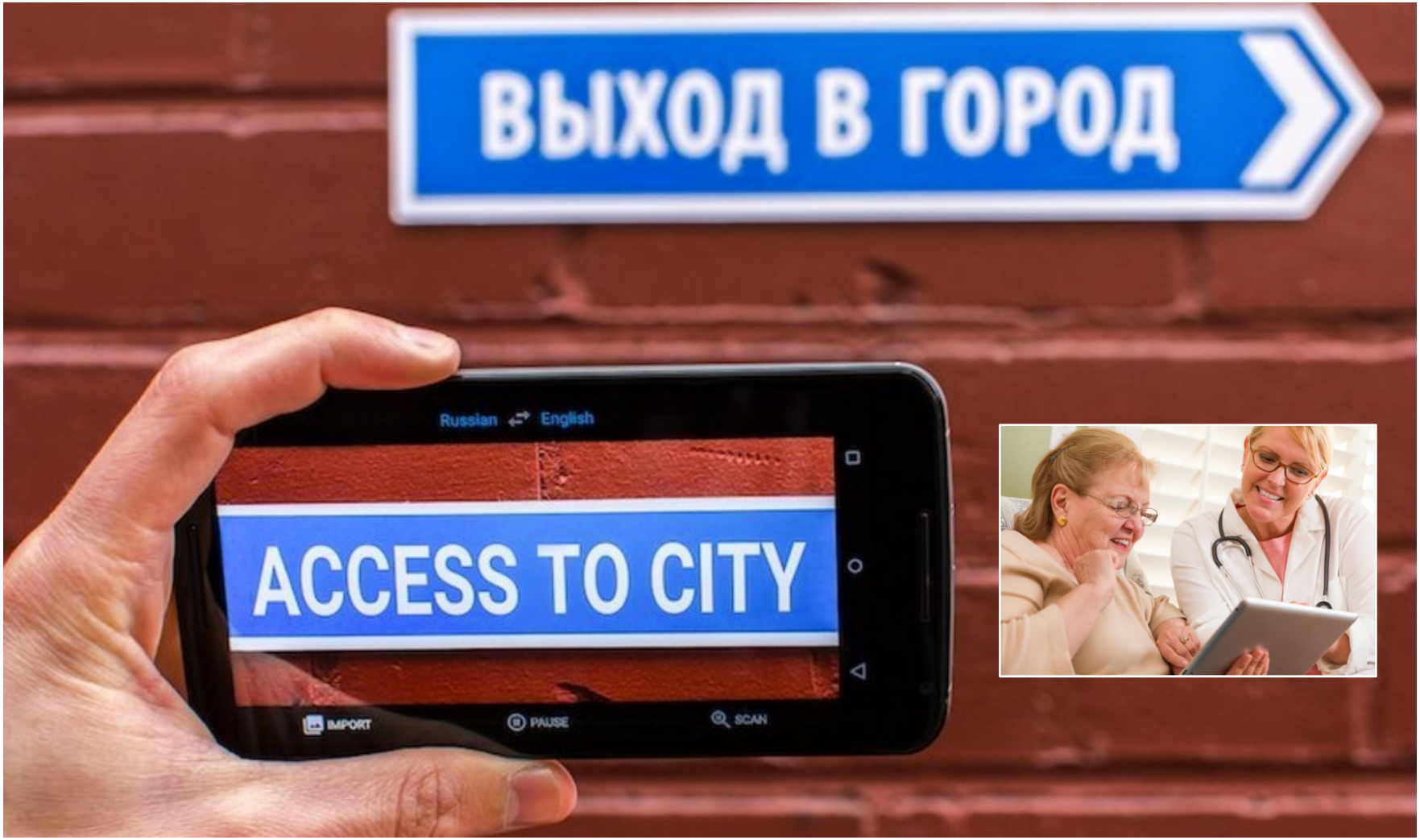
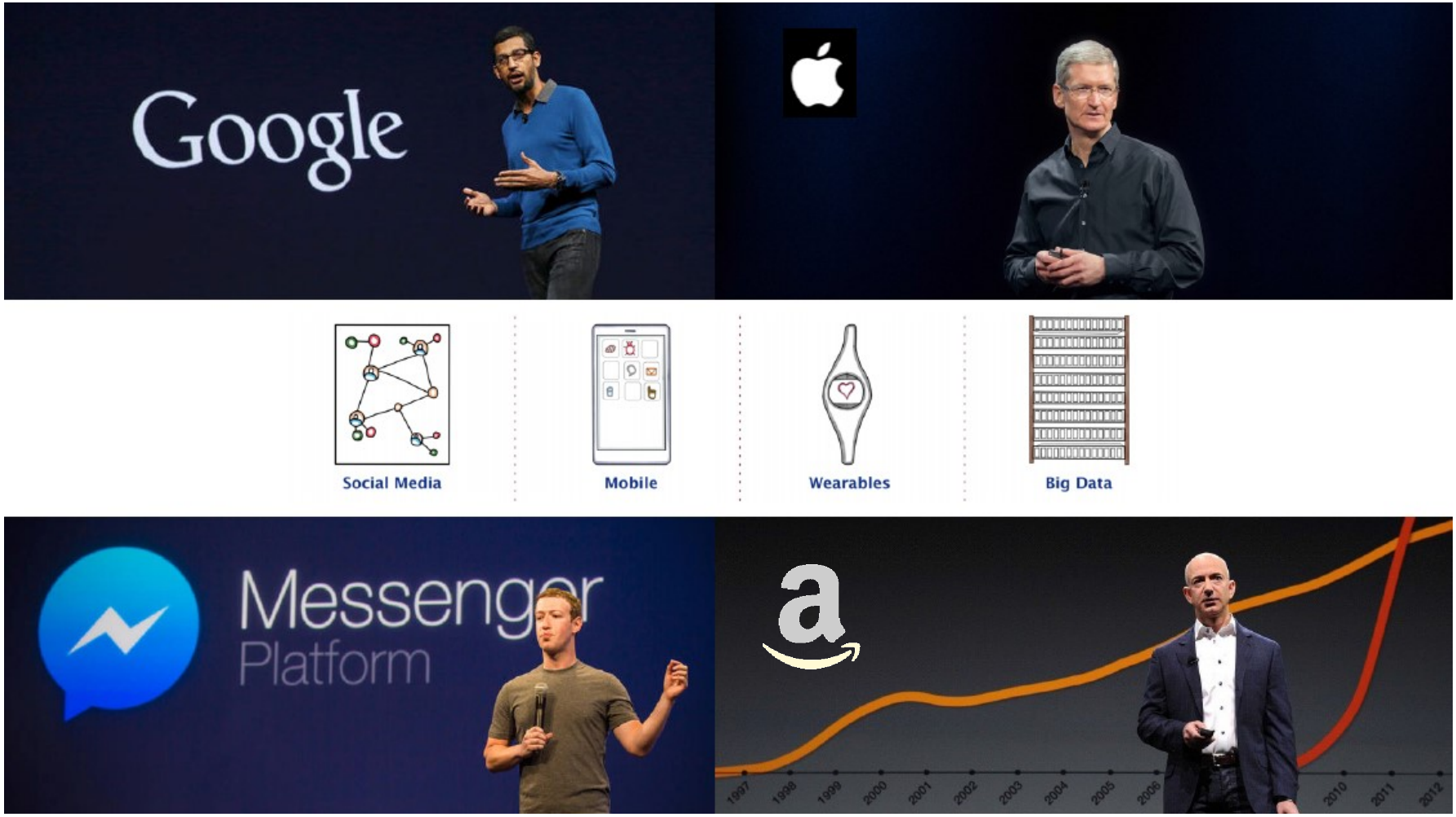
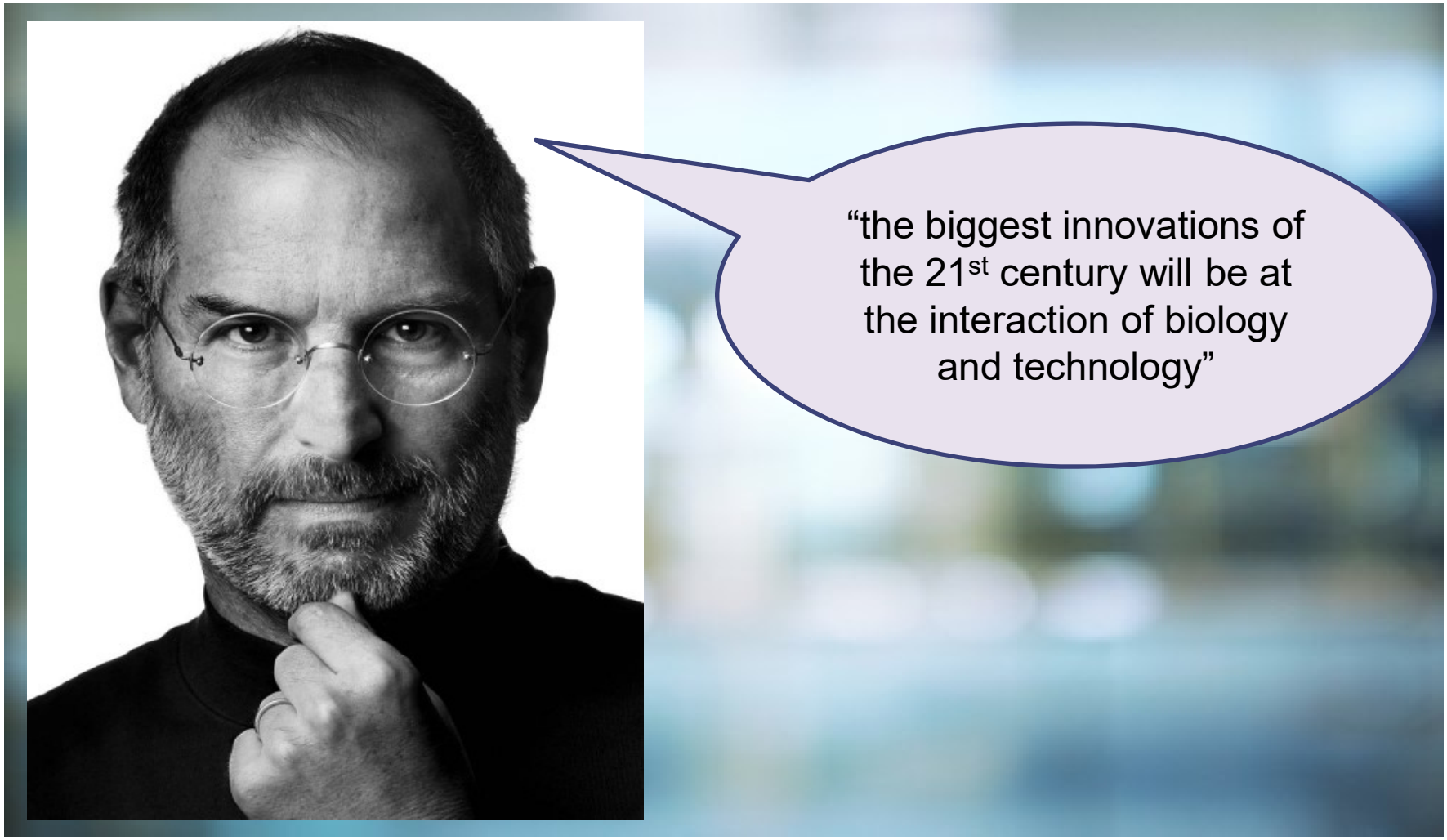
TECHNOLOGIES THAT MEET END USER NEEDS GENERATE OUTCOMES THAT MATTER TO PEOPLE

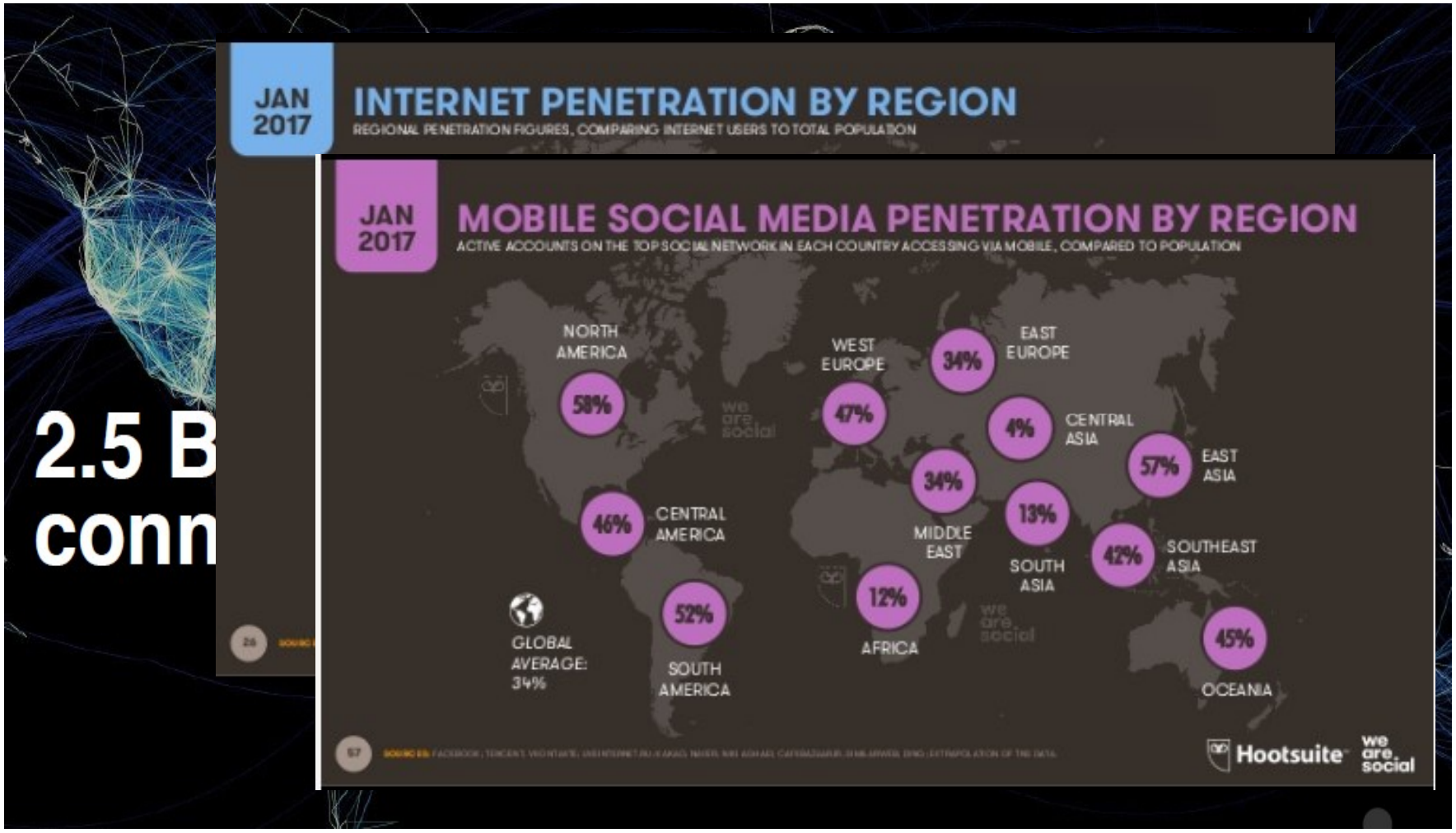


CONNECTIVITY OFFERS MULTIPLE OPPORTUNITIES TO GENERATE AND PROCESS PEOPLE EXPERIENCE DATA

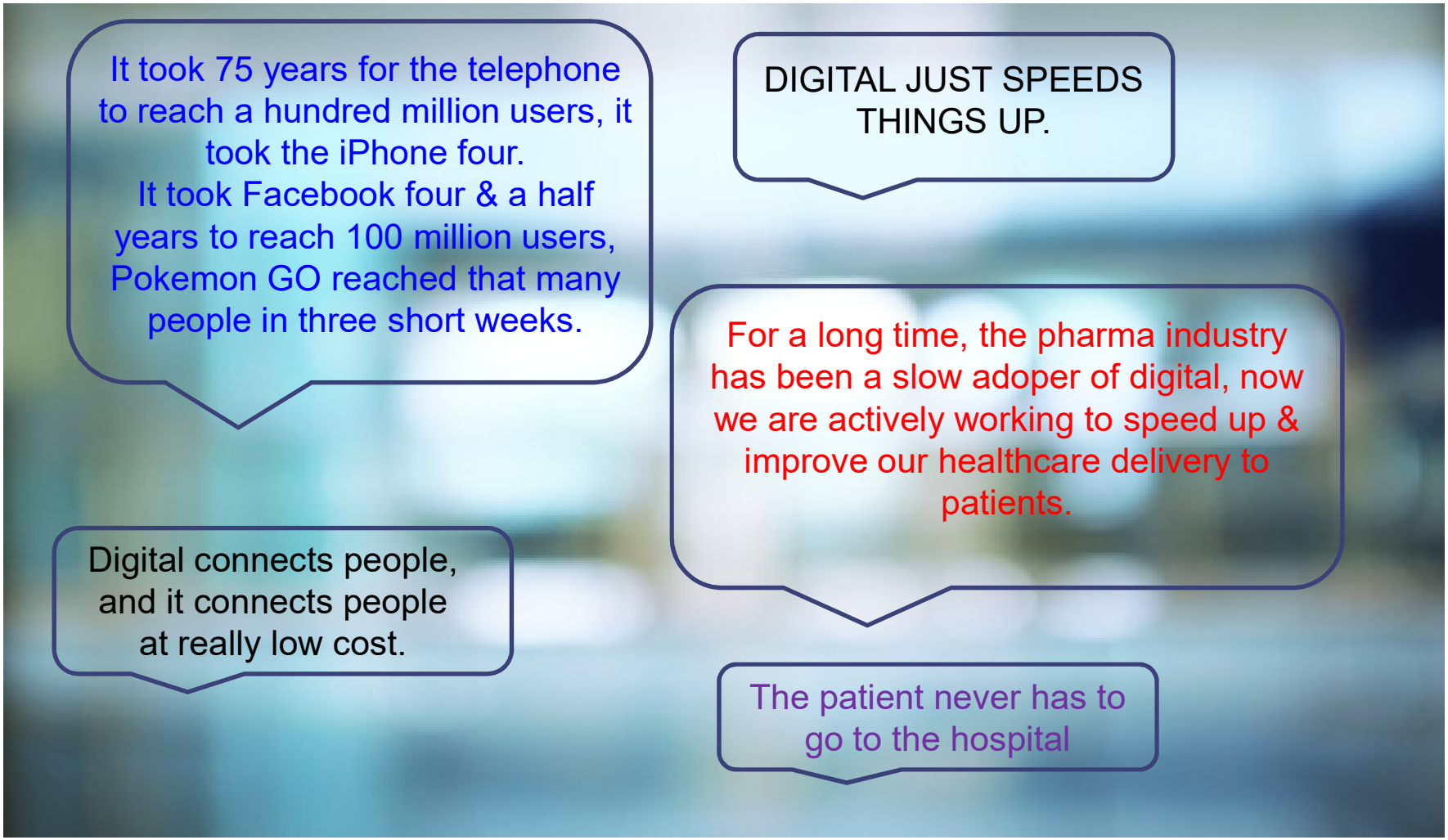



“the biggest innovations of the 21st century will be at the interaction of biology and technology”

DIGITAL TECHNOLOGY EMPOWERS PEOPLE IN AN INCREASINGLY CONNECTED WORLD



SOME KEY MESSAGES FROM THE SANOFI TOP MANAGERS



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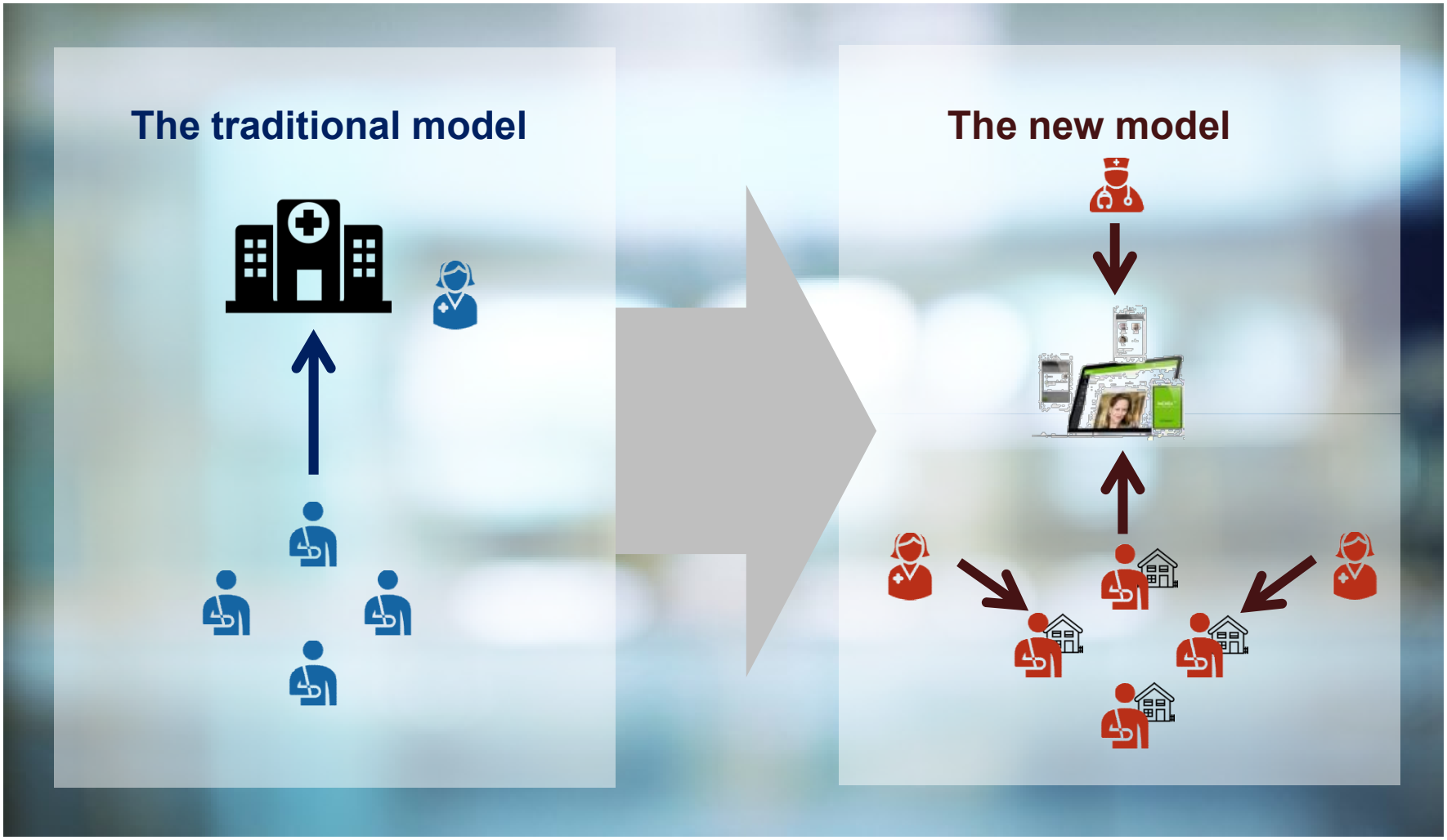
DISTRIBUTED STUDIES ARE OPENING NEW POSSIBILITIES IN CLINICAL TRIAL DESIGN



The patient never has to go to the hospital

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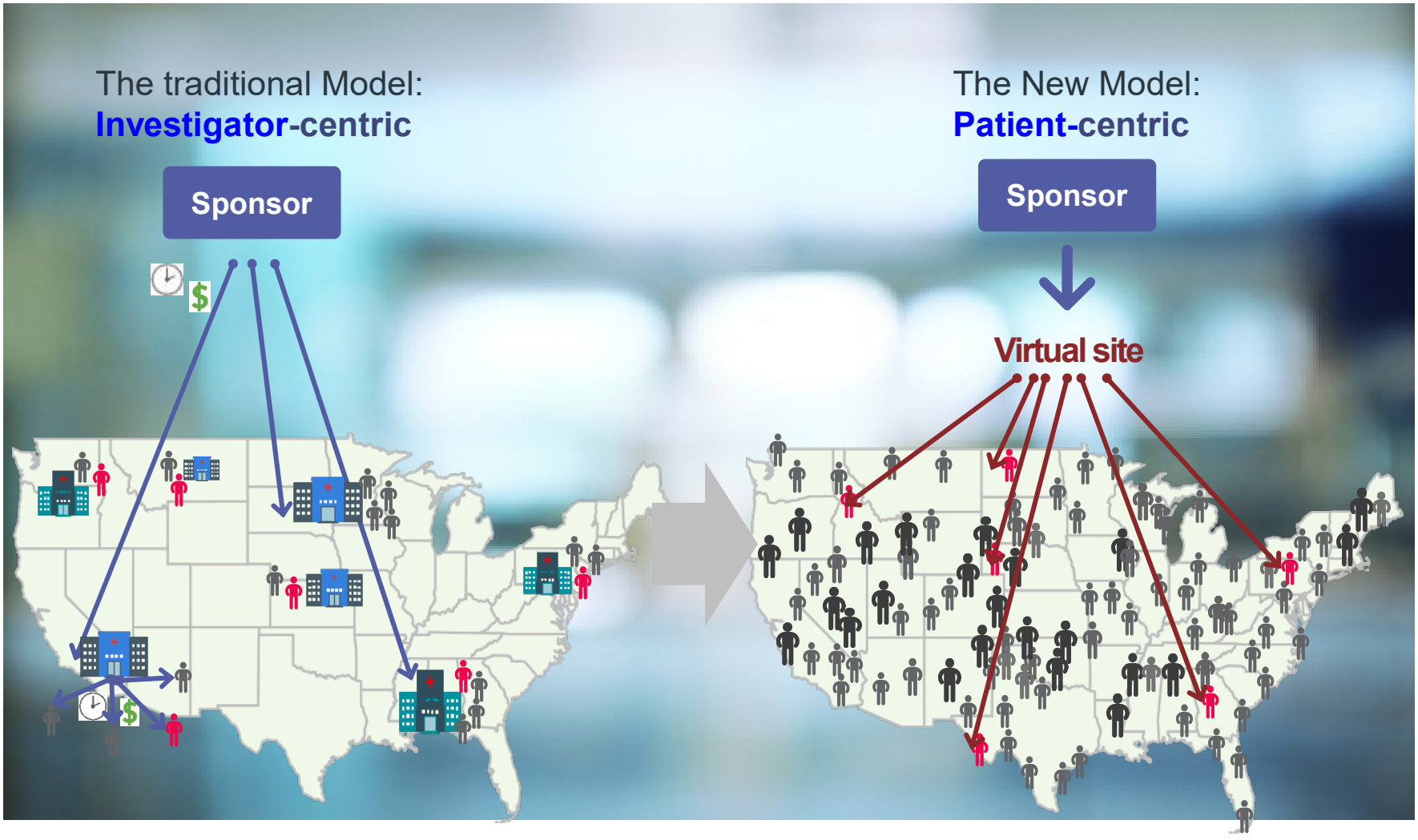

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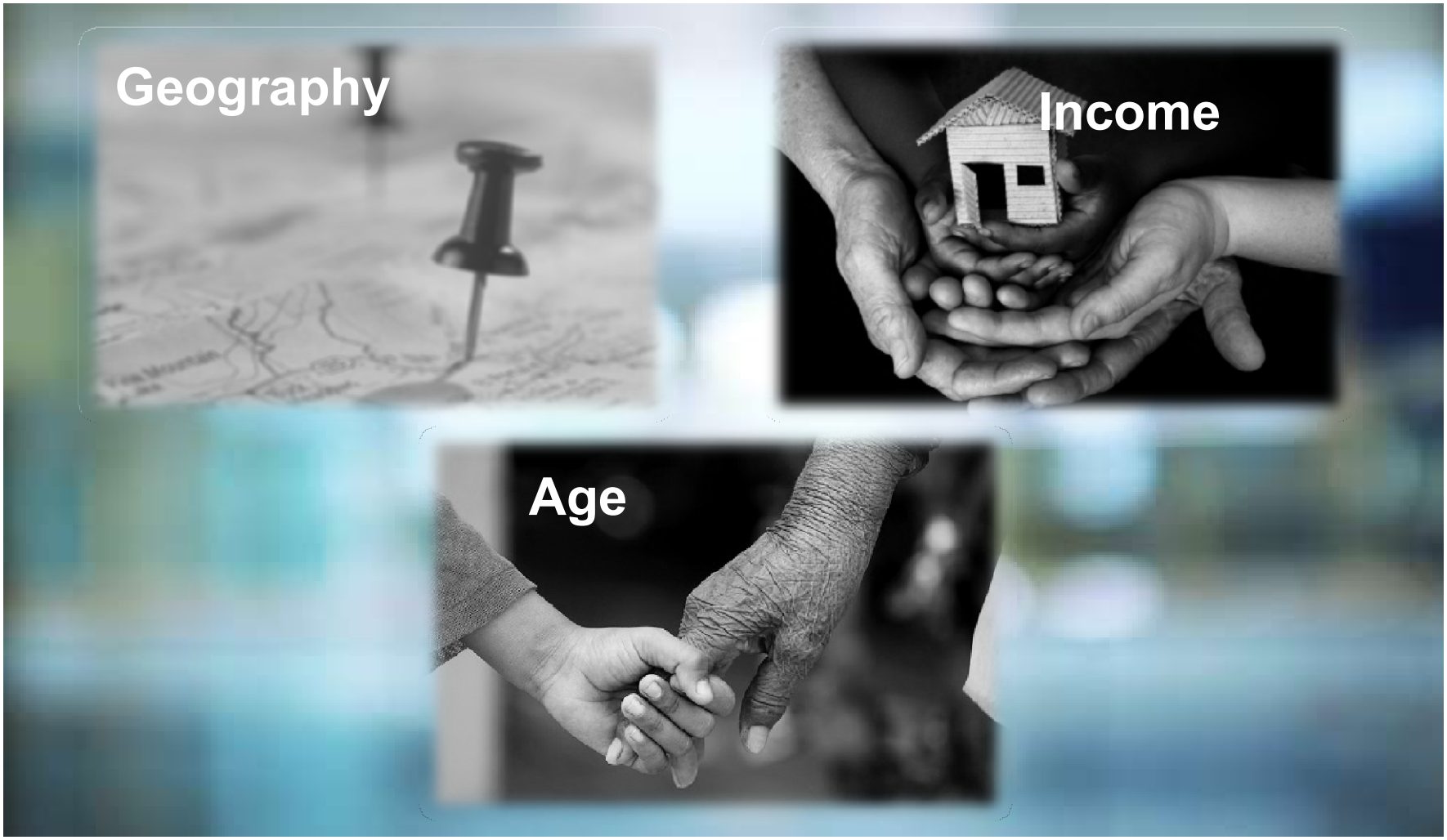
REMOTE, TECHNOLOGY-ENABLED TRIAL DESIGN IS INCLUSIVE TO POPULATIONS WE COULD NOT EASILY REACH SO FAR



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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

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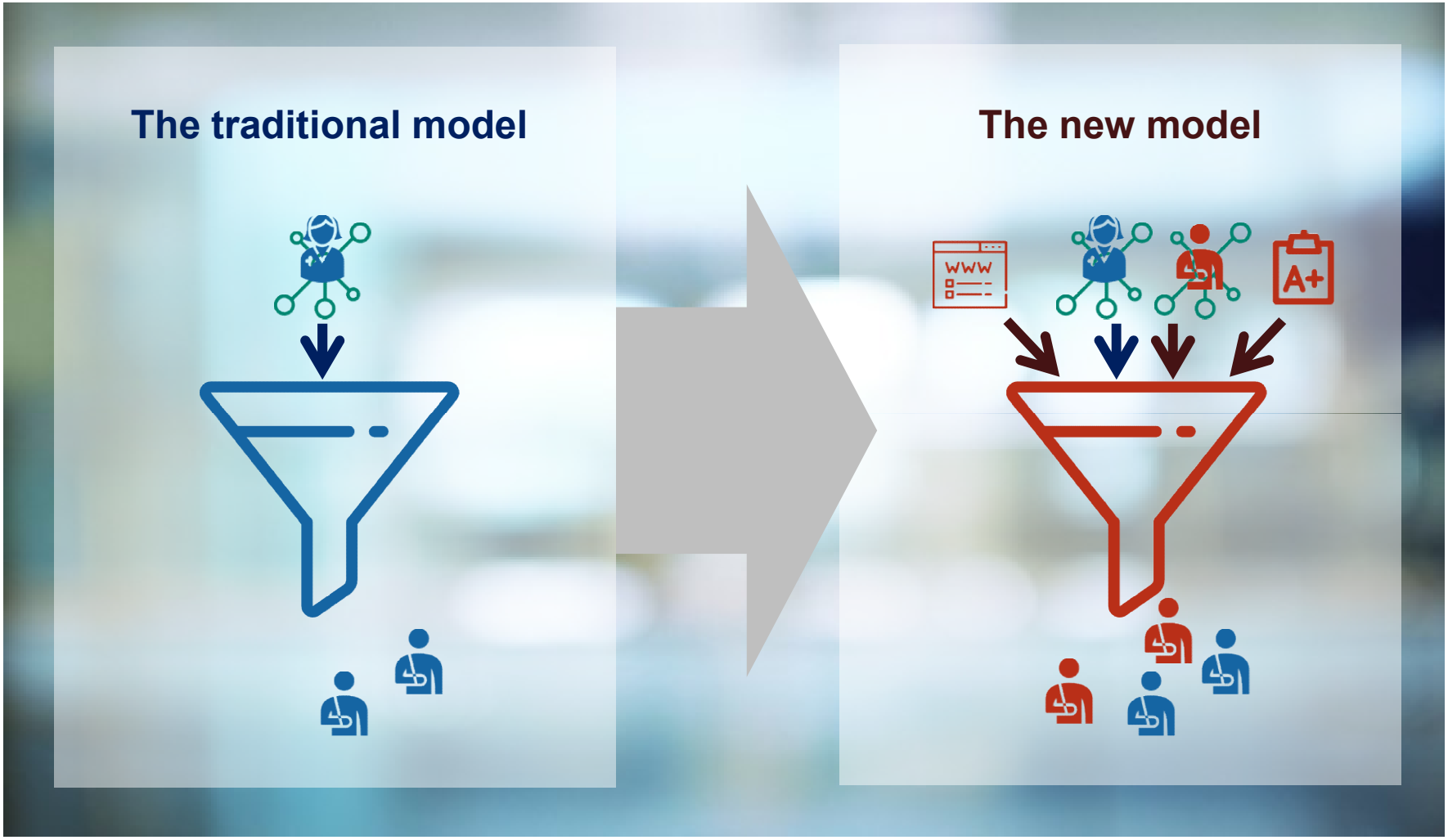
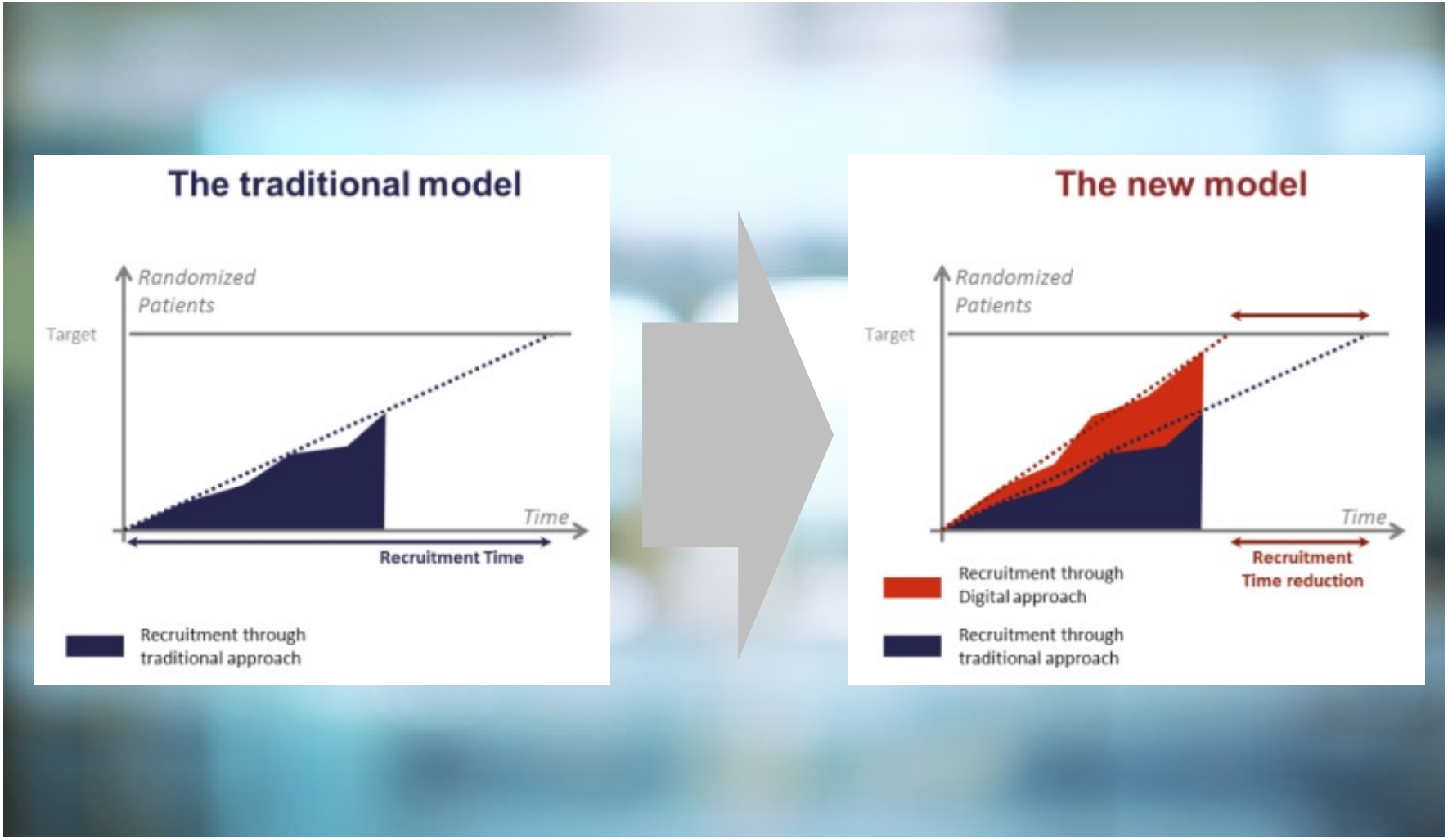
TRADITIONAL PATIENT RECRUITMENT METHODS OFTEN FAIL TO ATTRACT PATIENTS



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

TRADITIONAL MODEL VS NEW MODEL



MULTI-CHANNEL RECRUITMENT & DATA MANAGEMENT IMPACT

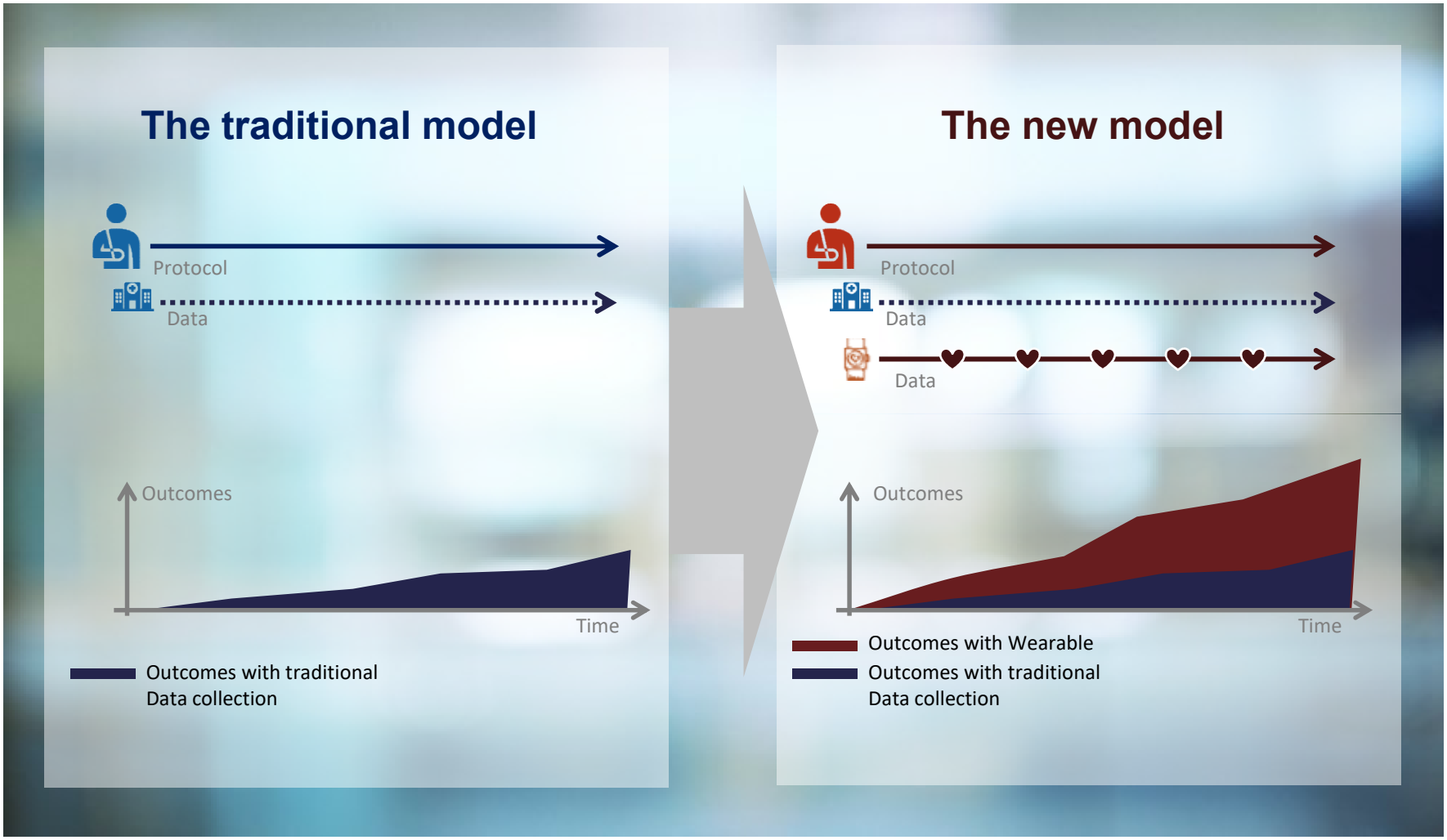
EXPECTED BENEFITS:

- ✓ 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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EHR: electronic health record

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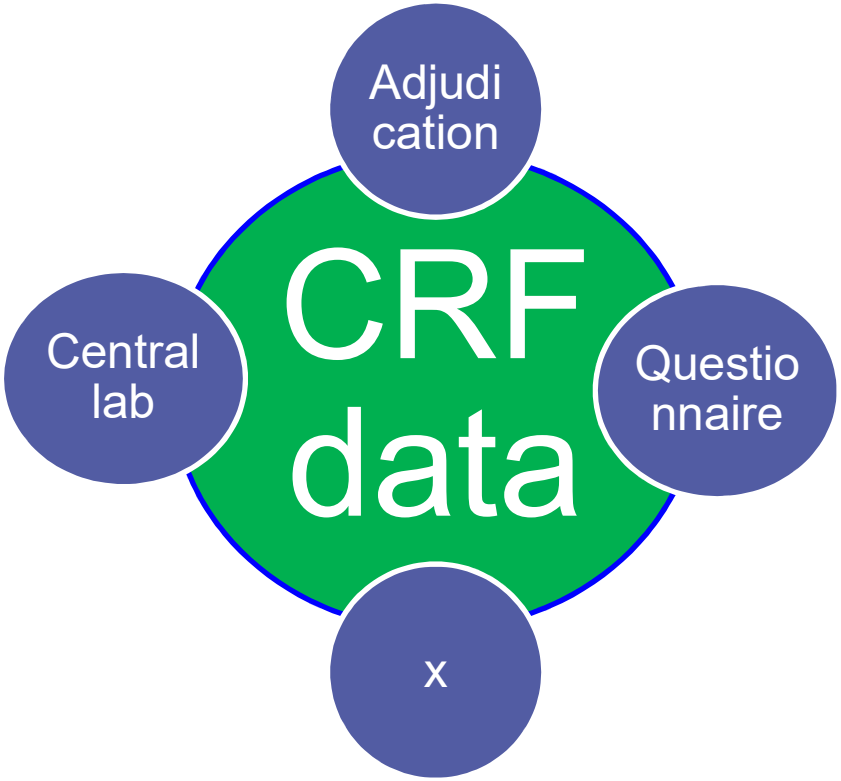
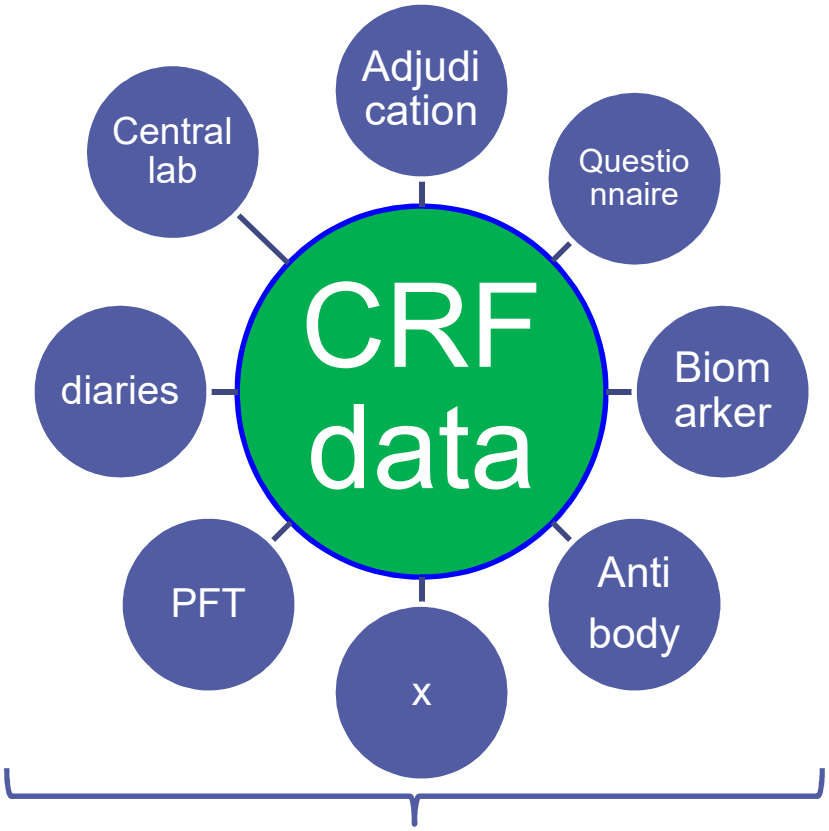
EVOLUTION OF THE DATA COLLECTION

PAST



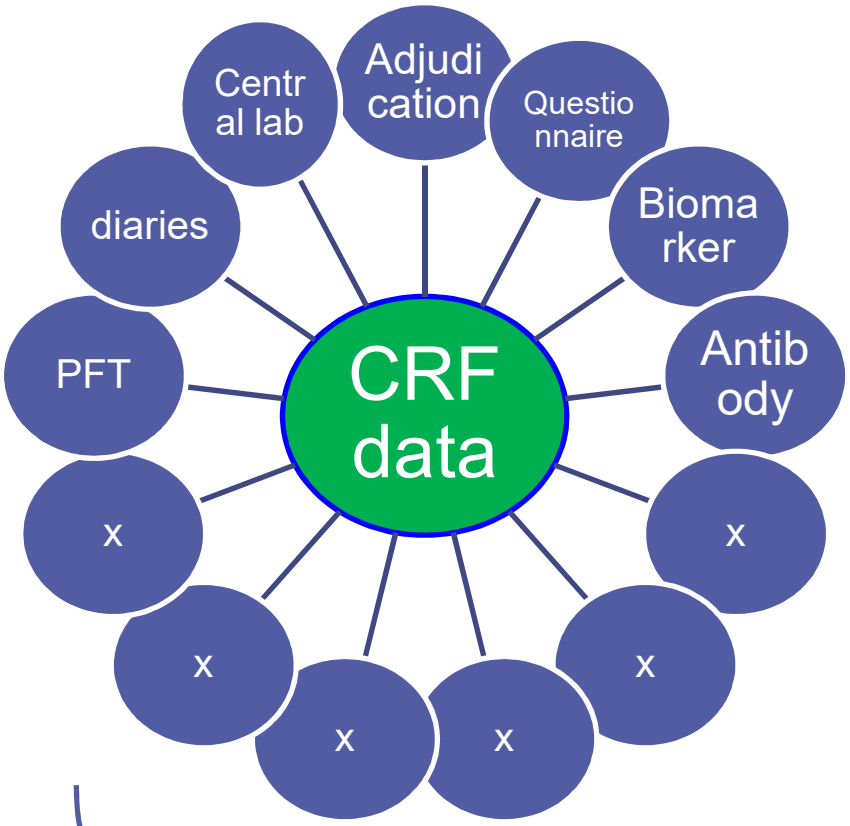
PRESENT



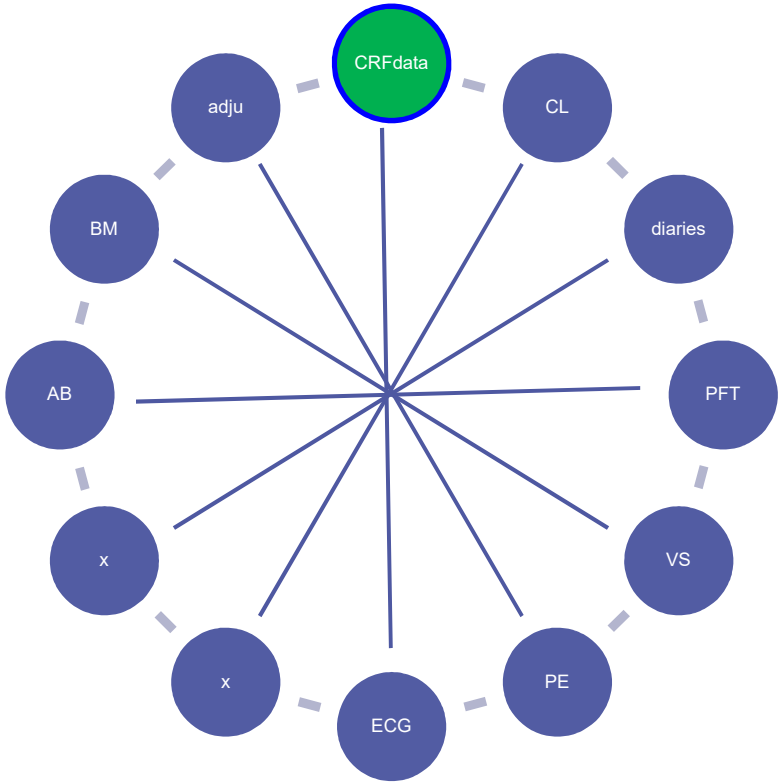
Do we have the appropriate IT landscape ?

EVOLUTION OF THE DATA COLLECTION

FUTURE 1



FUTURE 2



Will we still need an EDC ?

CHALLENGES & CONCLUSION

BACK UP SLIDES

VIVA
TECHNOLOGY
STARTUP CONNECT / PARIS 2017

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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

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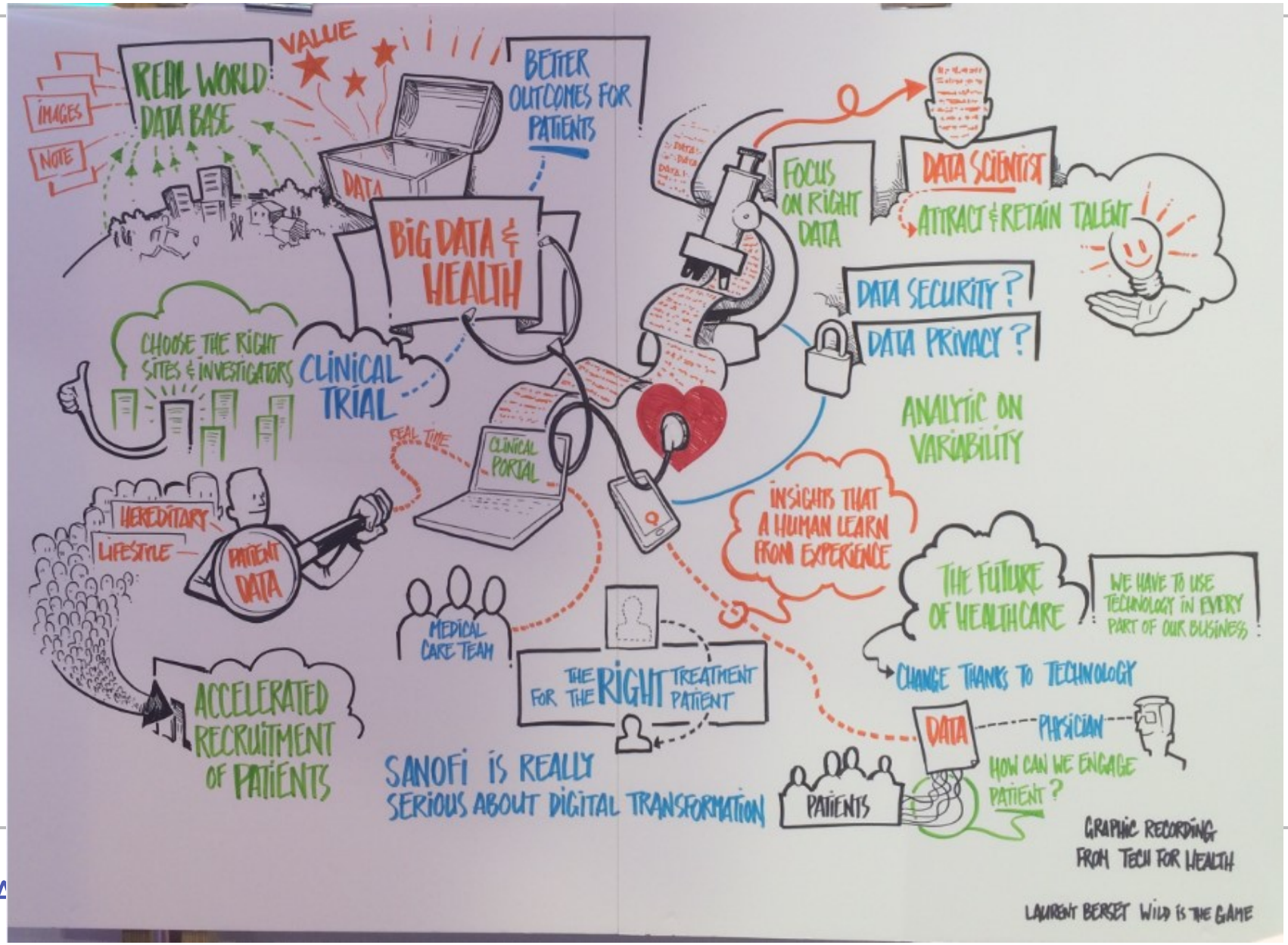

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