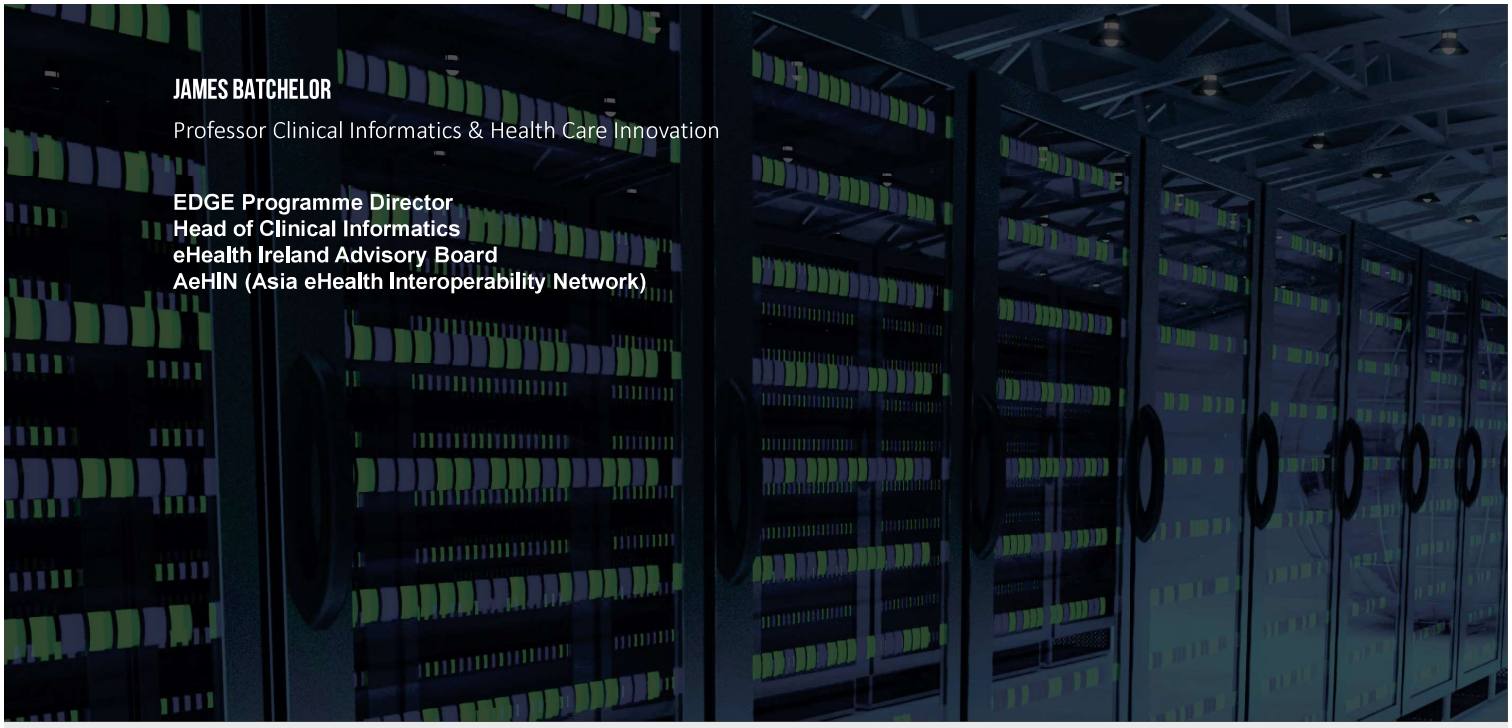
# PRINCIPLES OF INTEGRATION OF LABORATORY AND CLINICAL INFORMATION

UNIVERSITY OF Southampton




**JAMES BATCHELOR**

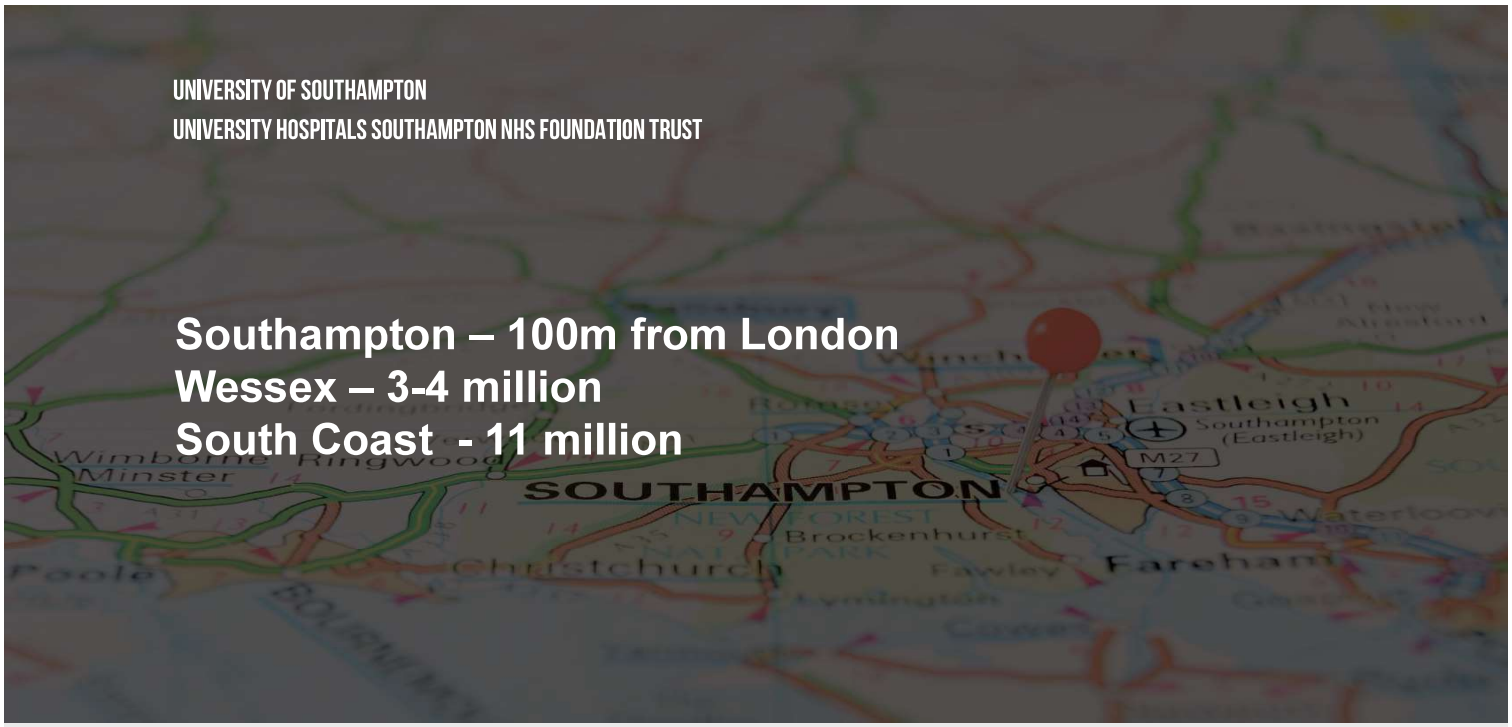
Professor Clinical Informatics & Health Care Innovation

**EDGE Programme Director**
**Head of Clinical Informatics**
**eHealth Ireland Advisory Board**
**AeHIN (Asia eHealth Interoperability Network)**

UNIVERSITY OF SOUTHAMPTON

UNIVERSITY HOSPITALS SOUTHAMPTON NHS FOUNDATION TRUST

# Southampton – 100m from London
# Wessex – 3-4 million
# South Coast - 11 million




## 100K WHOLE GENOME

**10 Dec 2012**

UK PM launched a Government initiative to achieve a paradigm shift in the way that genomics is used across the Healthcare.

Commitment to sequence 100,000 whole human genomes in rare/inherited diseases and certain common cancers.

Additional commitment to support the educational needs of workforce and to socialise the genome through active PPI.

## 100,000 Whole Genome Sequences with linked data

### Objective 1

Increased discovery of pathogenic variants leading to new treatments, devices and diagnostics

### Objective 2

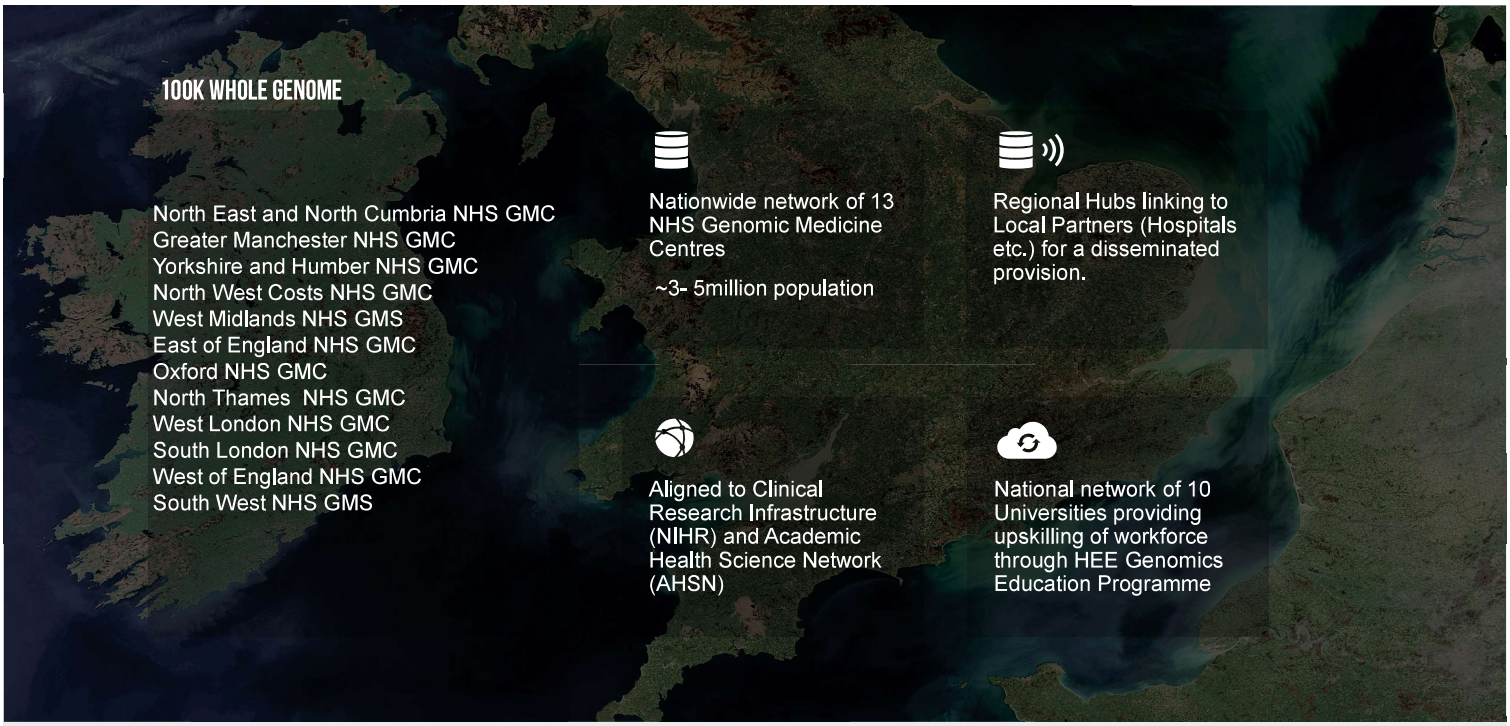
Accelerate uptake with advanced genomic medicine practice integrated into the NHS

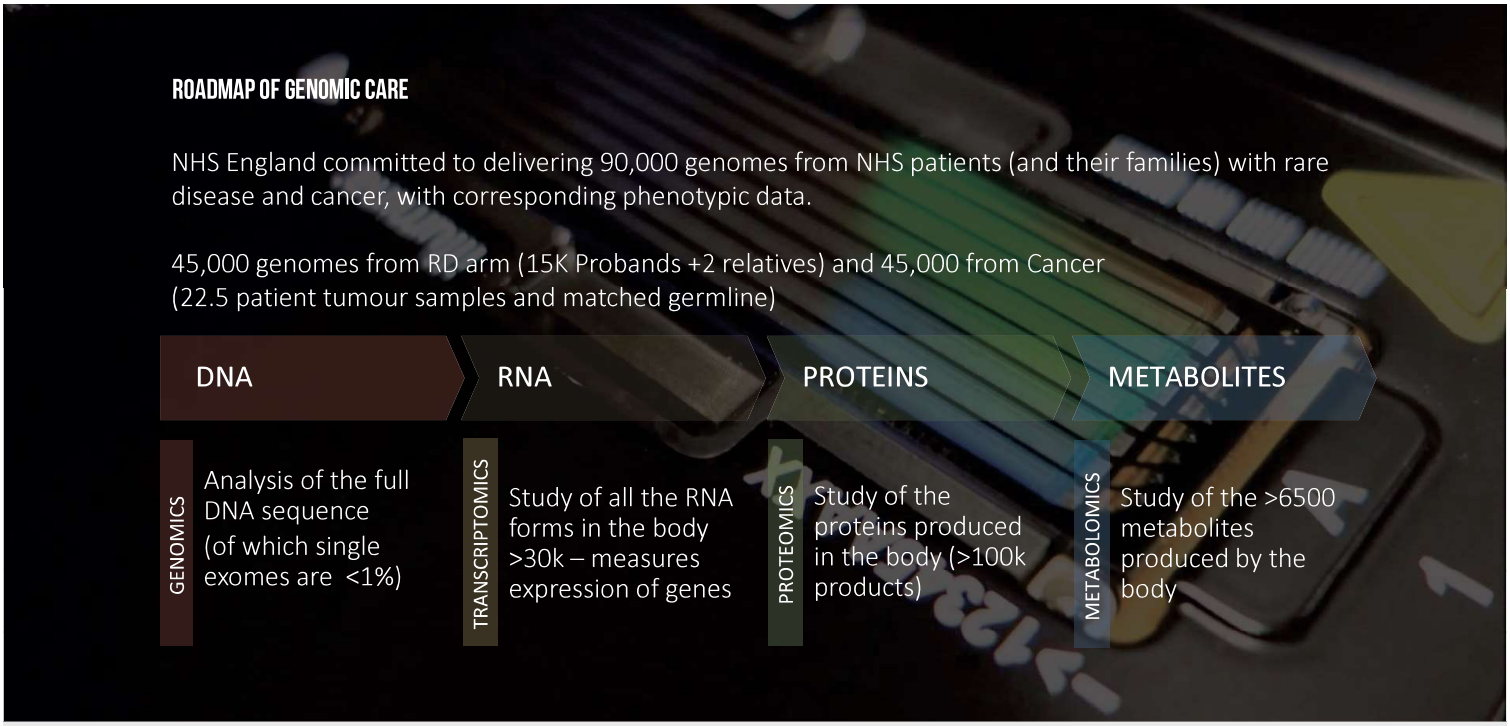
### Objective 3

Increase public understanding and support for genomic medicine

### Objective 4

Stimulate and advance UK life sciences industry and commercial activity in genomics


100K WHOLE GENOME
North East and North Cumbria NHS GMC
Greater Manchester NHS GMC
Yorkshire and Humber NHS GMC
North West Costs NHS GMC
West Midlands NHS GMS
East of England NHS GMC
Oxford NHS GMC
North Thames NHS GMC
West London NHS GMC
South London NHS GMC
West of England NHS GMC
South West NHS GMS
Nationwide network of 13 NHS Genomic Medicine Centres
~3- 5million population
Regional Hubs linking to Local Partners (Hospitals etc.) for a disseminated provision.
Aligned to Clinical Research Infrastructure (NIHR) and Academic Health Science Network (AHSN)
National network of 10 Universities providing upskilling of workforce through HEE Genomics Education Programme


ROADMAP OF GENOMIC CARE
NHS England committed to delivering 90,000 genomes from NHS patients (and their families) with rare disease and cancer, with corresponding phenotypic data.
45,000 genomes from RD arm (15K Probands +2 relatives) and 45,000 from Cancer (22.5 patient tumour samples and matched germline)
DNA
RNA
PROTEINS
METABOLITES
GENOMICS
Analysis of the full DNA sequence (of which single exomes are <1%)
TRANSCRIPTOMICS
Study of all the RNA forms in the body >30k – measures expression of genes
PROTEOMICS
Study of the proteins produced in the body (>100k products)
METABOLOMICS
Study of the >6500 metabolites produced by the body

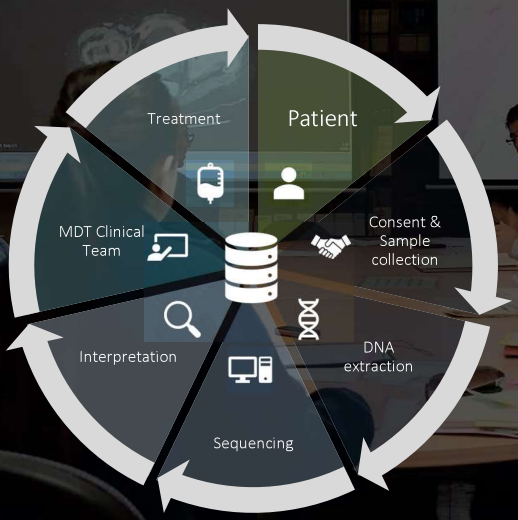
## ROADMAP OF GENOMIC CARE

**NHS Genomic Medicine Centers**

Rare diseases, cancers and pathogens
Broad consent, characteristics, pathology and samples molecular

| DNA & Multi-omics | Data Clinical | Data Sources |
|---|---|---|
| UK BioRepository. | Life-course registry Linked to anonymised whole Genome Sequence | Primary Care<br>Hospital episodes<br>Cancer Registries<br>Rare Disease Registries<br>Infectious Disease<br>Mortality data<br>Patient entry |
| **Commercial Sequencing Center** | **Data & Software Infrastructure** | |
| Illumina - £100 Million<br>Wellcome Trust £27 Million | MRC £24m Research Data Infrastructure (GeCIP) Sequential builds of pseudonymised data and WGS **Safe haven- users work within** | |
| **Users** | **Users** | **Users** |
| Clinicians & Academics | Training & capacity | Industry |

## ROADMAP OF GENOMIC CARE



## 100K PROJECT SOLUTIONS

**Independent Cancer Taskforce Report**

Drive to increase diagnostic capacity and develop new diagnostic approaches
Recommends a national molecular pathology service,
Recognises role of research and data as drivers of continuous improvement

**Precision Medicine**

NHS England has committed to the development of a personalised medicine strategy, informed by the development in genomics
Cancer is already a huge area for personalisation, with drug selection informed by the genetics of an individual's tumour

**Data & Networks**

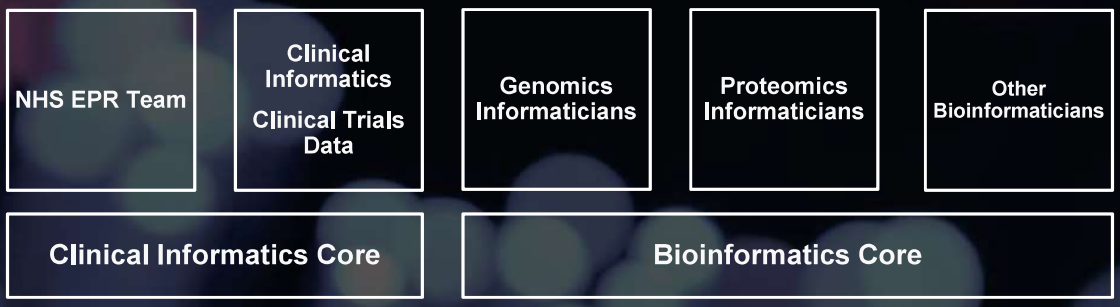
Informatics and shared reporting will play a major role in increasing the impact of care, bringing all the elements together to maximise knowledge about an individual and give the clearest picture of their condition

PROBLEM

**Shaping the future of care**

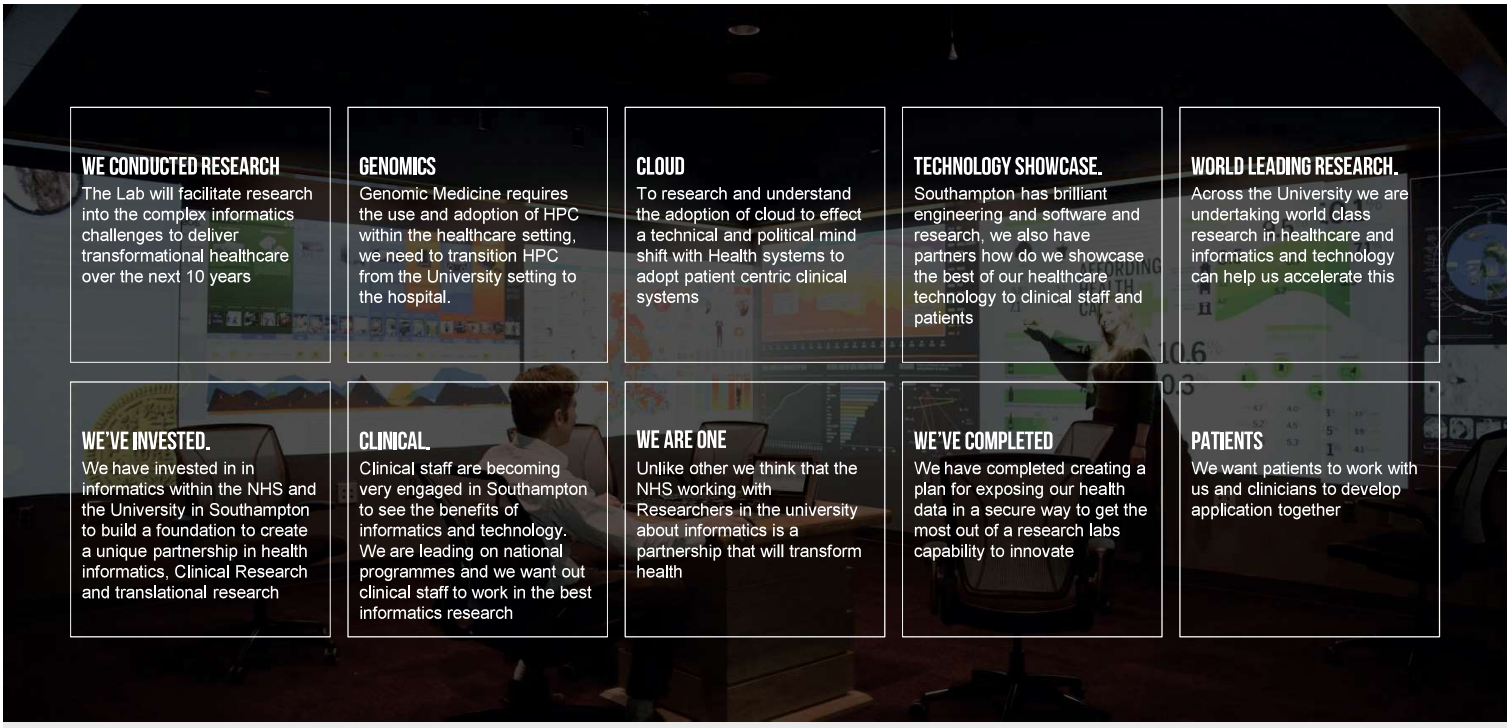
This work has impact beyond just the 100,000 Genomes Project stretching into the broader delivery of future care

## HOSPITAL & RESEARCH INFORMATICS



# OPEN PLAN CARE

Patient Centric Care



### WE CONDUCTED RESEARCH

The Lab will facilitate research into the complex informatics challenges to deliver transformational healthcare over the next 10 years

### GENOMICS

Genomic Medicine requires the use and adoption of HPC within the healthcare setting, we need to transition HPC from the University setting to the hospital.

### CLOUD

To research and understand the adoption of cloud to effect a technical and political mind shift with Health systems to adopt patient centric clinical systems

### TECHNOLOGY SHOWCASE.

Southampton has brilliant engineering and software and research, we also have partners how do we showcase the best of our healthcare technology to clinical staff and patients

### WORLD LEADING RESEARCH.

Across the University we are undertaking world class research in healthcare and informatics and technology can help us accelerate this

### WE'VE INVESTED.

We have invested in in informatics within the NHS and the University in Southampton to build a foundation to create a unique partnership in health informatics, Clinical Research and translational research

### CLINICAL.

Clinical staff are becoming very engaged in Southampton to see the benefits of informatics and technology. We are leading on national programmes and we want out clinical staff to work in the best informatics research

### WE ARE ONE

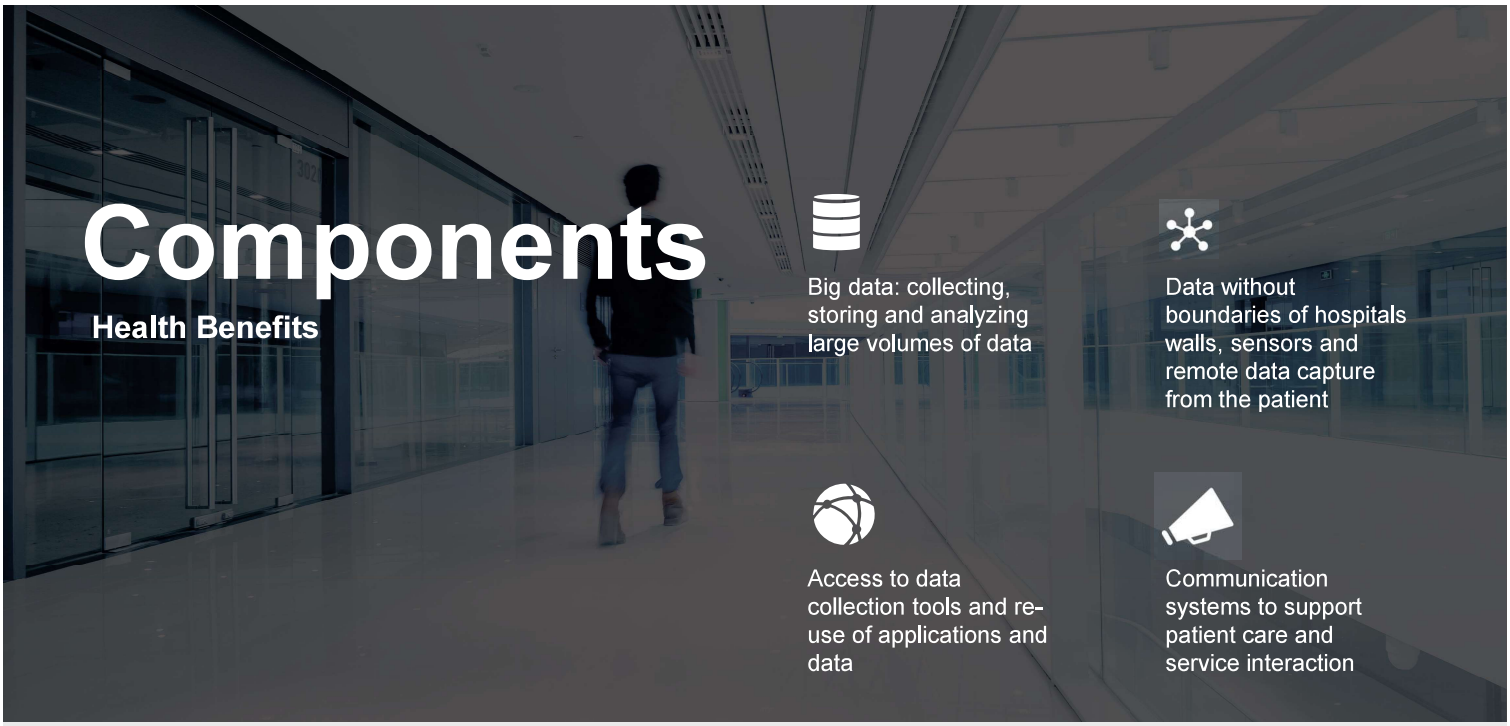
Unlike other we think that the NHS working with Researchers in the university about informatics is a partnership that will transform health

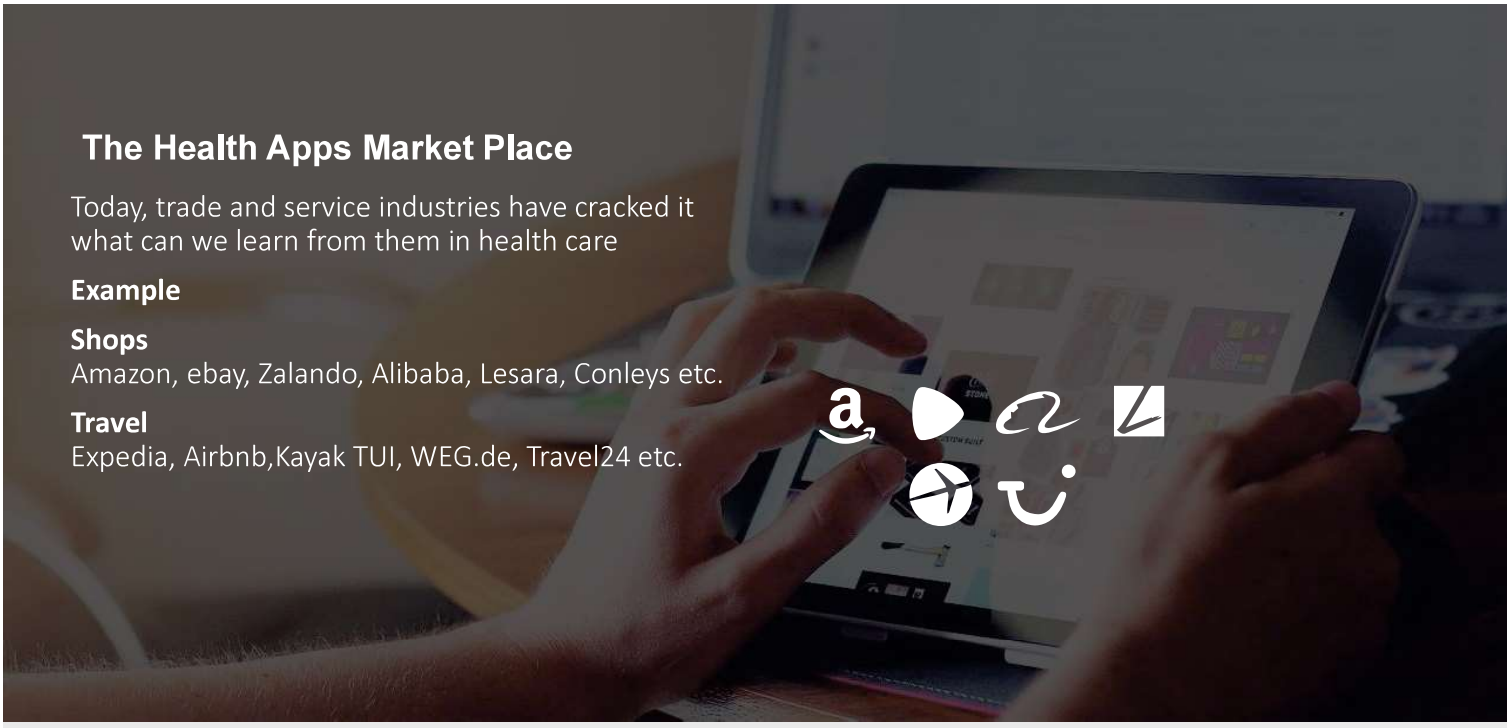
### WE'VE COMPLETED

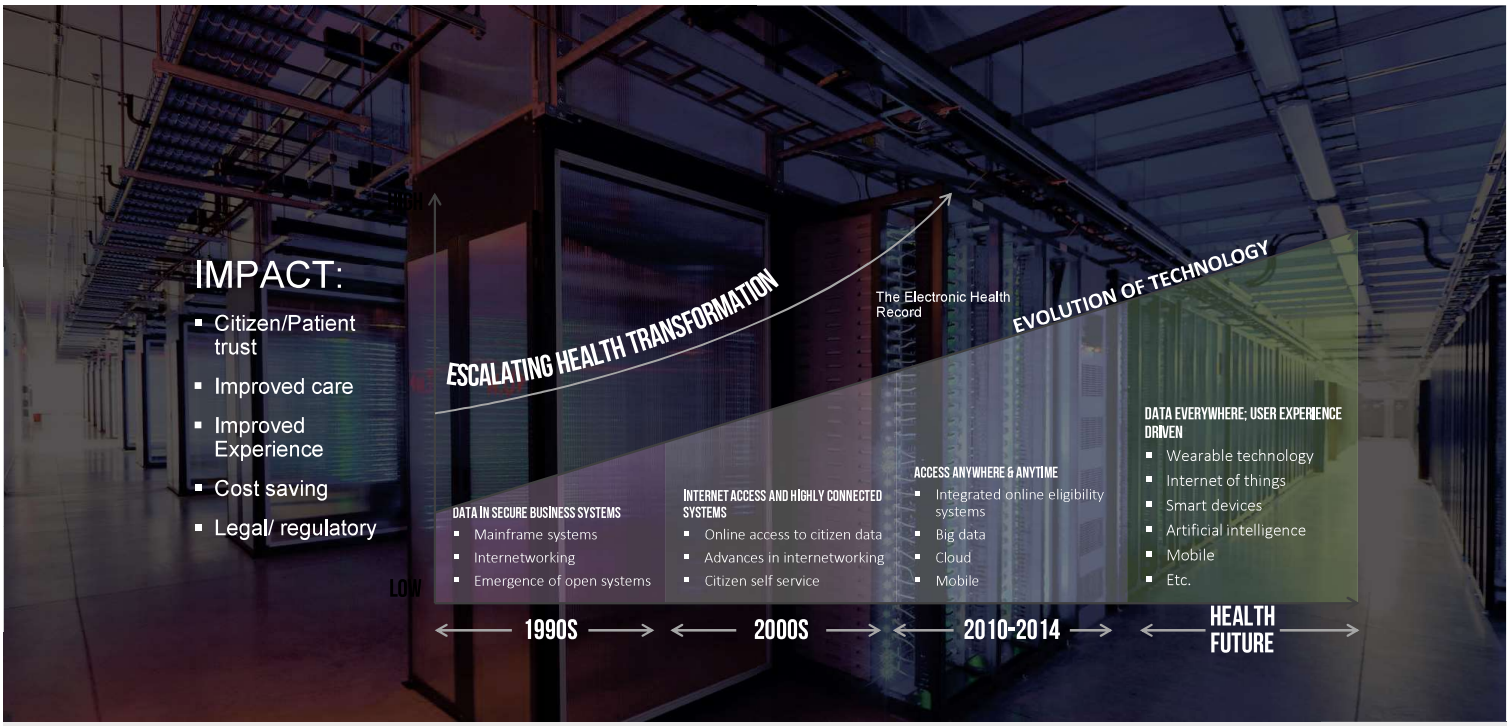
We have completed creating a plan for exposing our health data in a secure way to get the most out of a research labs capability to innovate

### PATIENTS

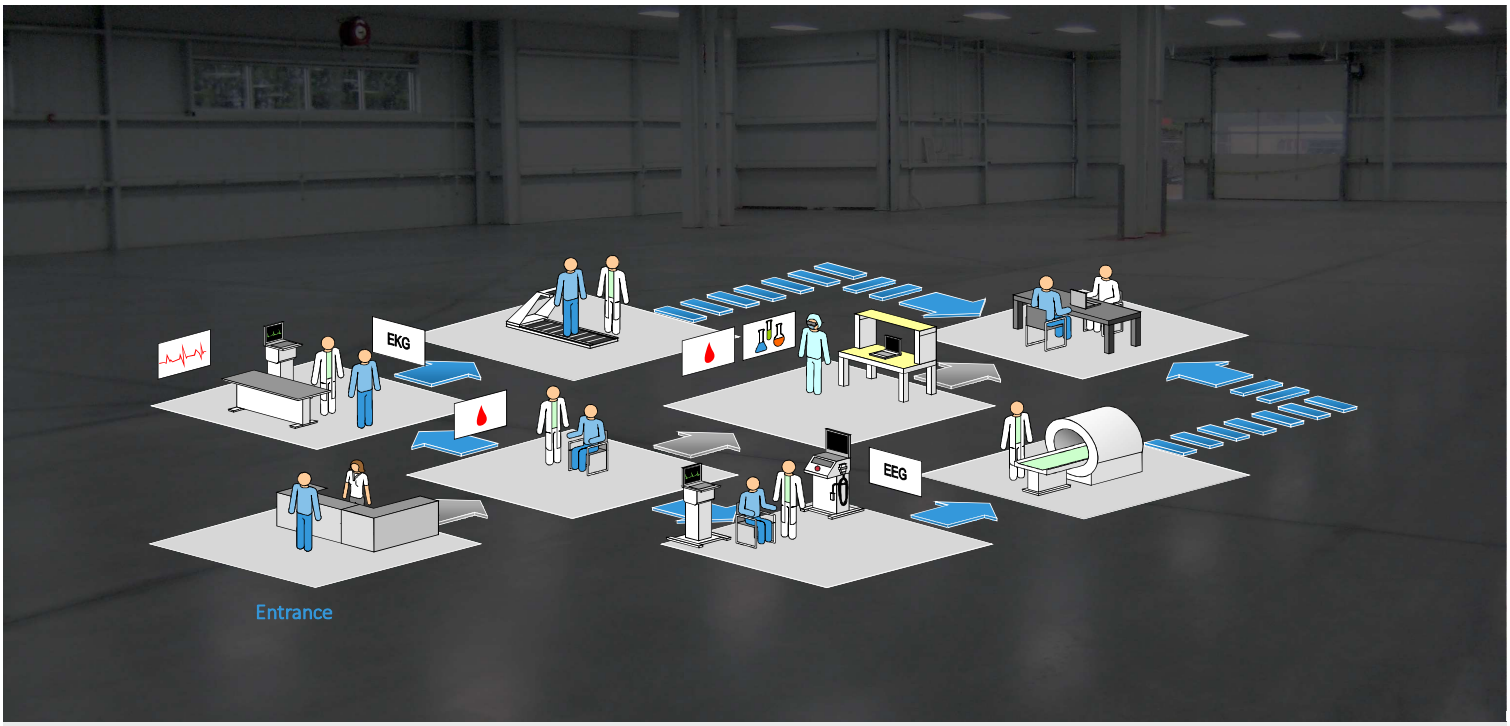
We want patients to work with us and clinicians to develop application together

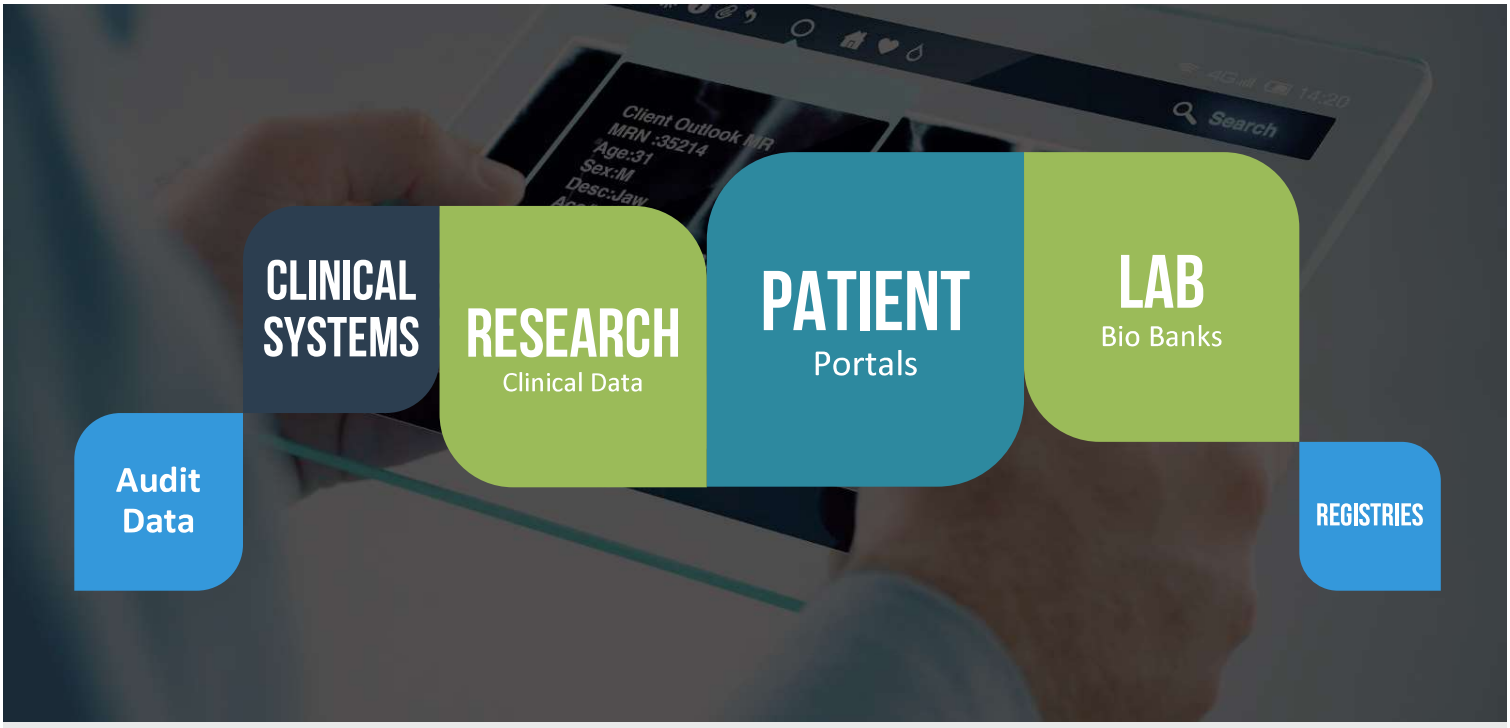

Components
Health Benefits
Big data: collecting, storing and analyzing large volumes of data
Data without boundaries of hospitals walls, sensors and remote data capture from the patient
Access to data collection tools and re-use of applications and data
Communication systems to support patient care and service interaction

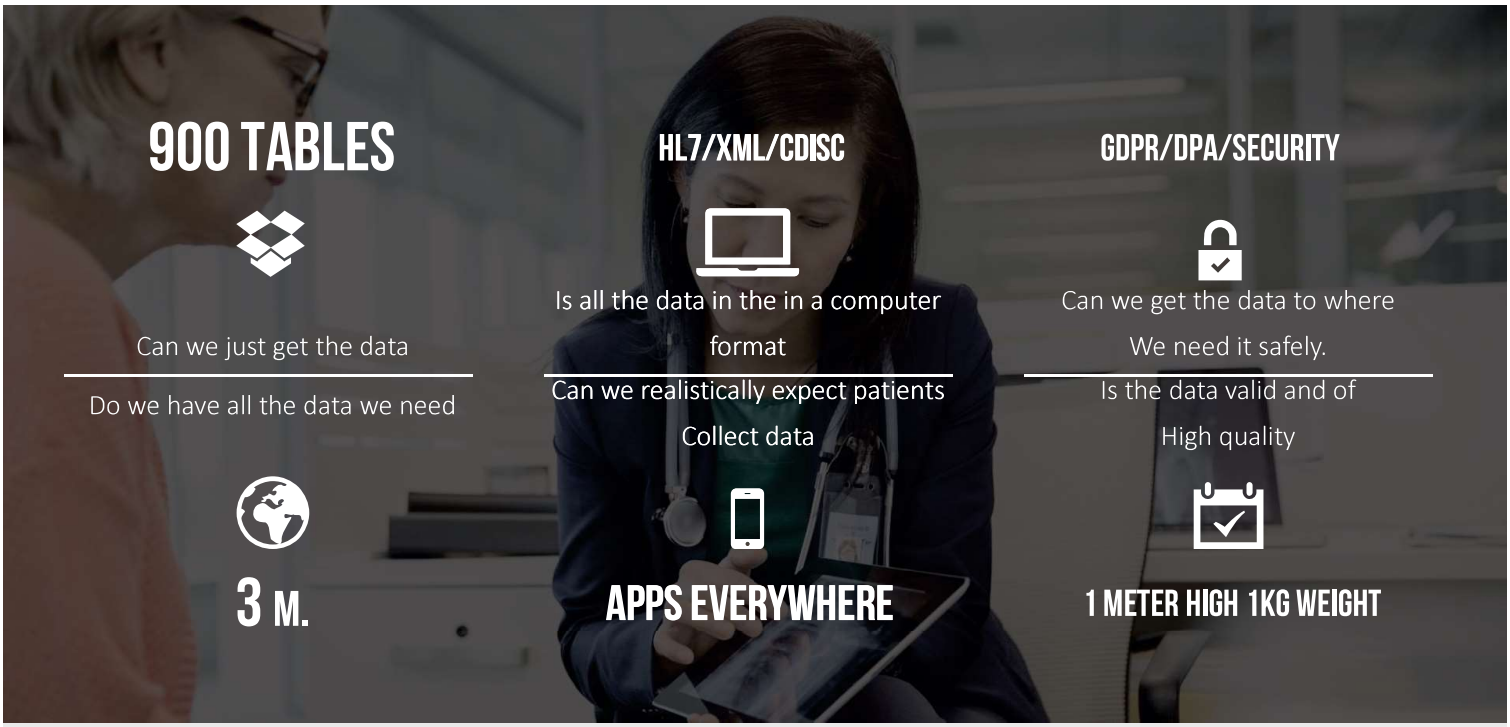

The Health Apps Market Place
Today, trade and service industries have cracked it what can we learn from them in health care
Example
Shops
Amazon, ebay, Zalando, Alibaba, Lesara, Conleys etc.
Travel
Expedia, Airbnb,Kayak TUI, WEG.de, Travel24 etc.

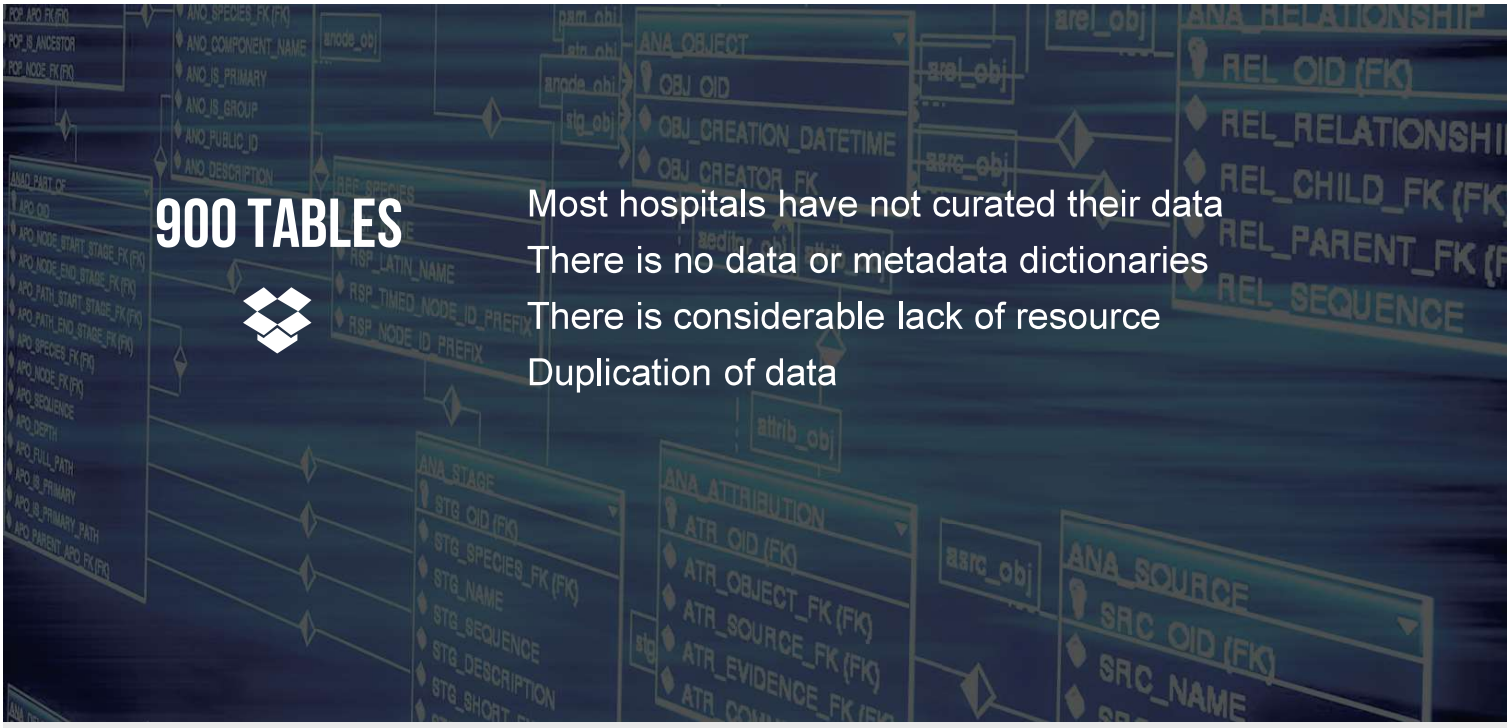

IMPACT:
Citizen/Patient trust
Improved care
Improved Experience
Cost saving
Legal/ regulatory
HIGH
LOW
ESCALATING HEALTH TRANSFORMATION
EVOLUTION OF TECHNOLOGY
The Electronic Health Record
DATA IN SECURE BUSINESS SYSTEMS
Mainframe systems
Internetworking
Emergence of open systems
INTERNET ACCESS AND HIGHLY CONNECTED SYSTEMS
Online access to citizen data
Advances in internetworking
Citizen self service
ACCESS ANYWHERE & ANYTIME
Integrated online eligibility systems
Big data
Cloud
Mobile
DATA EVERYWHERE; USER EXPERIENCE DRIVEN
Wearable technology
Internet of things
Smart devices
Artificial intelligence
Mobile
Etc.
1990S
2000S
2010-2014
HEALTH FUTURE

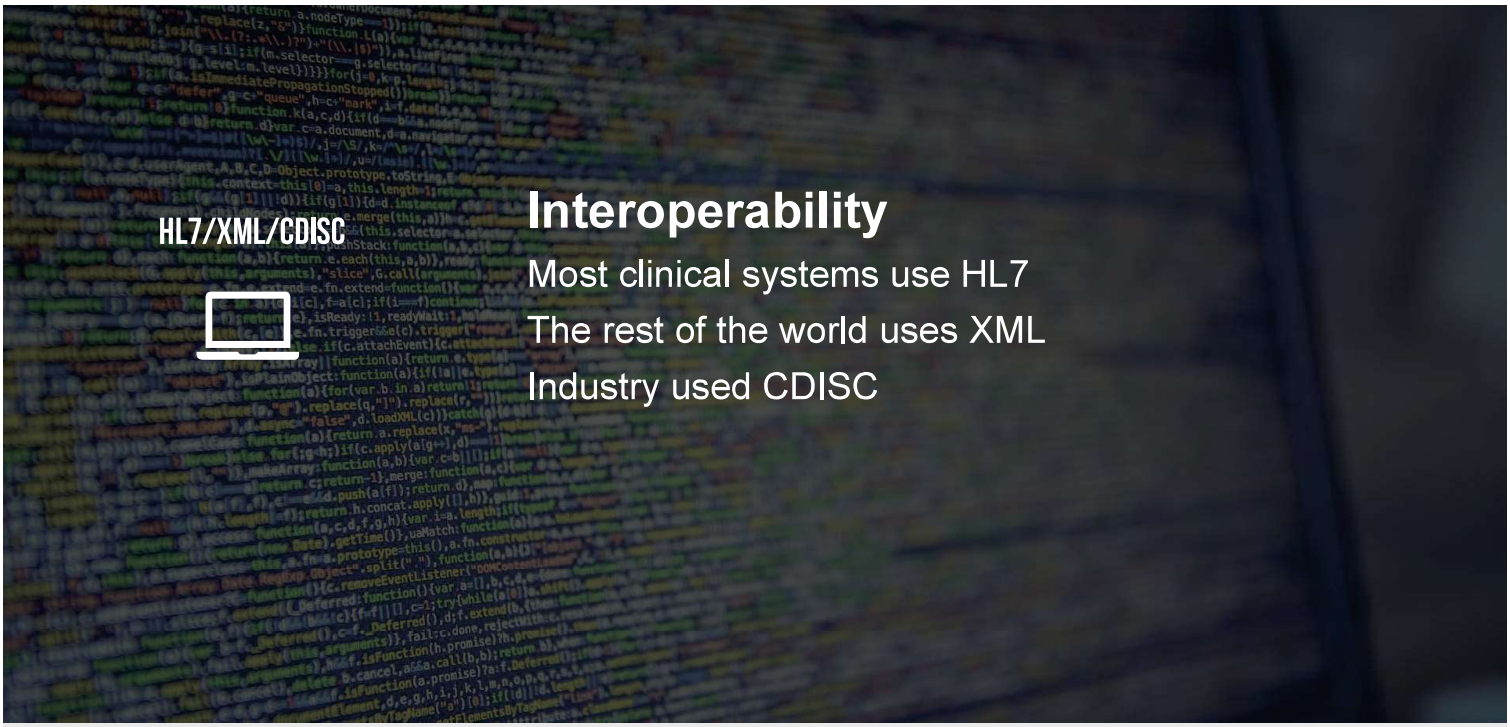

WE MIGHT BE
A LITTLE BIT BEHIND


EKG
EEG
Entrance


CLINICAL SYSTEMS
RESEARCH
Clinical Data
PATIENT
Portals
LAB
Bio Banks
Audit Data
REGISTRIES


900 TABLES
Can we just get the data
Do we have all the data we need
3 M.
HL7/XML/CDISC
Is all the data in the in a computer format
Can we realistically expect patients Collect data
APPS EVERYWHERE
GDPR/DPA/SECURITY
Can we get the data to where We need it safely.
Is the data valid and of High quality
1 METER HIGH 1KG WEIGHT


900 TABLES
Most hospitals have not curated their data
There is no data or metadata dictionaries
There is considerable lack of resource
Duplication of data




## Interoperability

Most clinical systems use HL7

The rest of the world uses XML

Industry used CDISC


## Security

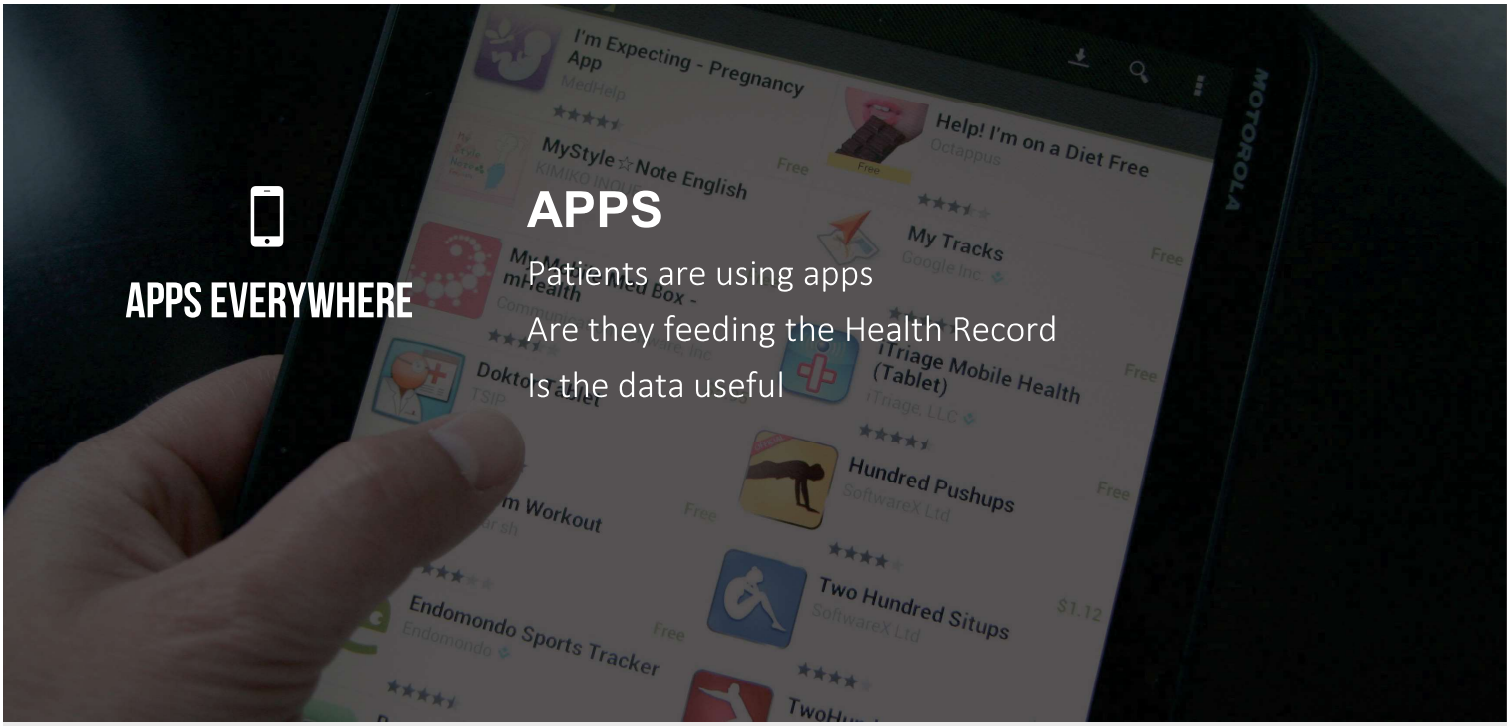
Public concerns

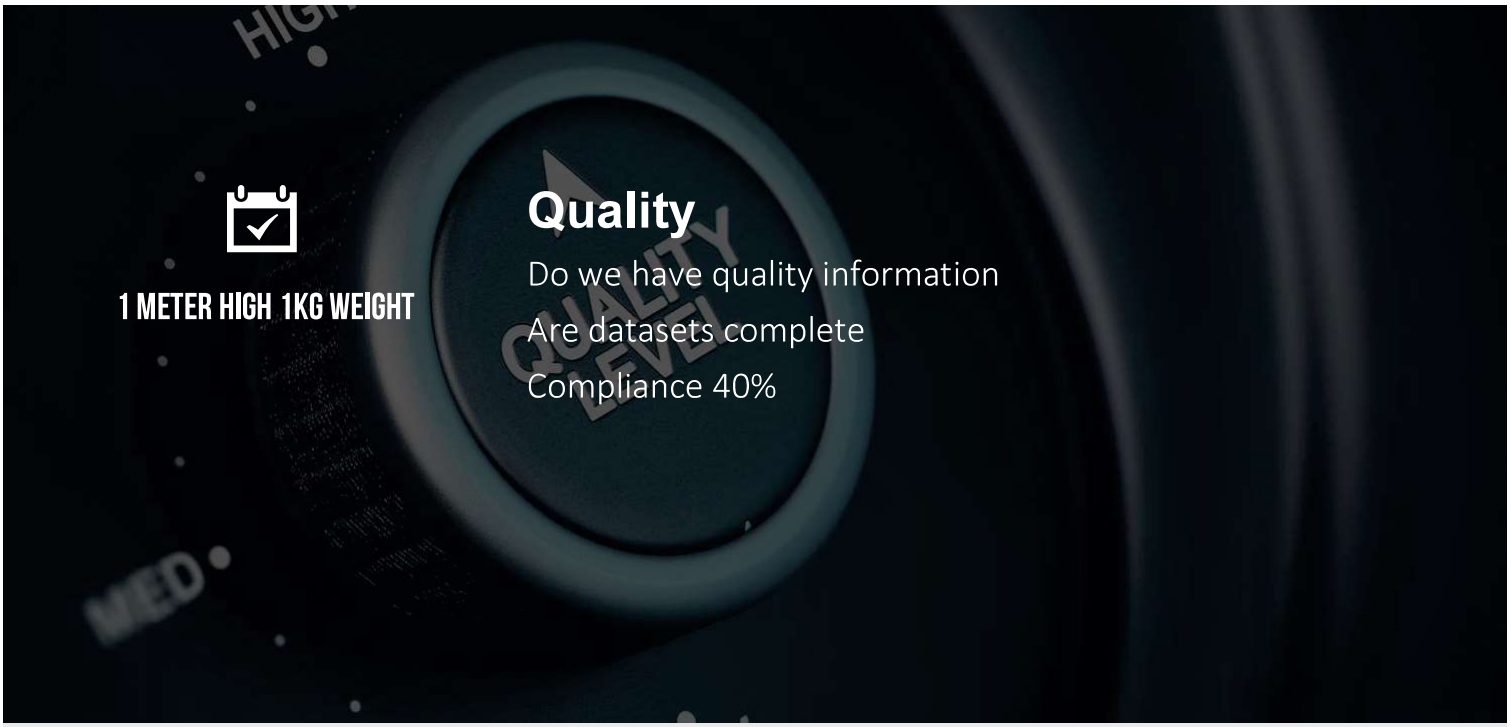
Public Trust

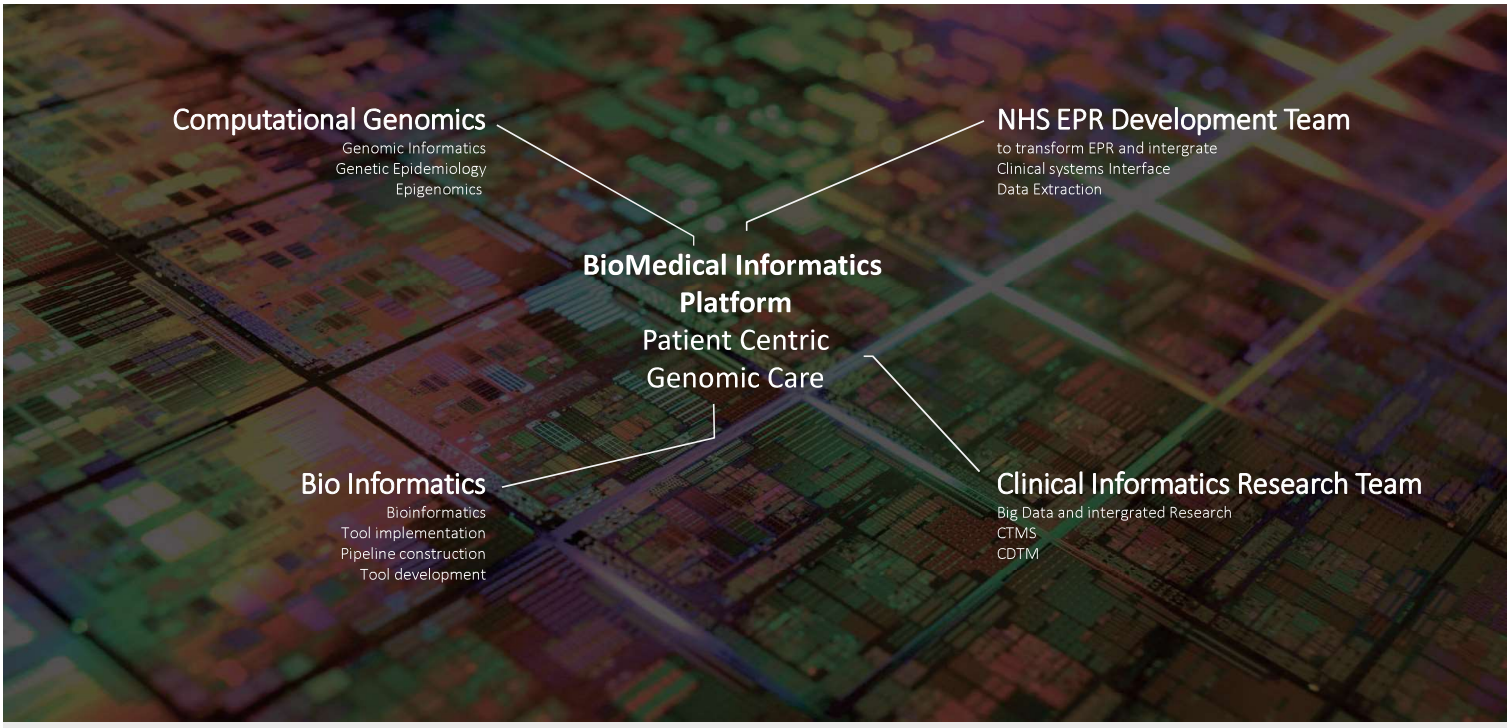
Onerous NHS requirements

Regulations


3 M.
3million Variables
Humans are complex
Tricky to explain
THE COMPACT EDITION OF THE OXFORD ENGLISH DICTIONARY
VOLUME I A-O


APPS EVERYWHERE
APPS
Patients are using apps
Are they feeding the Health Record
Is the data useful
I'm Expecting - Pregnancy App
MedHelp
Help! I'm on a Diet Free
Octappus
MyStyle Note English
My Tracks
Google Inc.
iTriage Mobile Health (Tablet)
iTriage, LLC
Hundred Pushups
SoftwareX Ltd
Two Hundred Situps
SoftwareX Ltd
$1.12
Endomondo Sports Tracker
Endomondo
MOTOROLA


1 METER HIGH 1KG WEIGHT
Quality
Do we have quality information
Are datasets complete
Compliance 40%

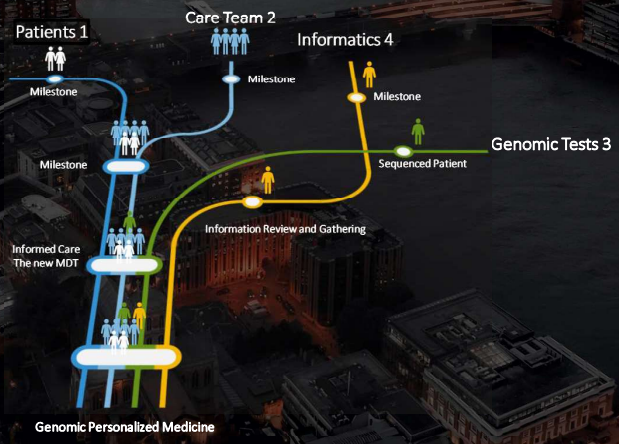

Computational Genomics
Genomic Informatics
Genetic Epidemiology
Epigenomics
NHS EPR Development Team
to transform EPR and intergrate
Clinical systems Interface
Data Extraction
BioMedical Informatics Platform
Patient Centric
Genomic Care
Bio Informatics
Bioinformatics
Tool implementation
Pipeline construction
Tool development
Clinical Informatics Research Team
Big Data and intergrated Research
CTMS
CDTM

# ROADMAP OF GENOMIC CARE

## Vision

Our care and information need to converge to ensure that we diliver

Intergrated Genomic Medcince




**EU** EU Clinical Trials Directive 2005/28/EC
Clinical trials performed in the European Union are required to be conducted in accordance with the Clinical Trials Directive

**UK** Medicines & Healthcare Products Regulatory Agency
UK ✓

**EU** EU Data Protection Directive
EU General Data Protection Regulation

**UK** UK Data Protection Act 1998 ✓
Information Commissioners office
Protect the rights of individuals and the use and processing of their personal information

**NHS** Hospital Information Governance & Data Protection Officer

**NHS** Hospital Based Polices and Procedures

**GOV** Government Protective Marking Scheme

**NHS** Caldecott Report

**NHS** Information Governance Toolkit ✓

Security Confidence
NHS like reassurance

☐ ICH GCP ✓

☐ Good Clinical Practice

☐ Good Manufacturing Practice

☐ Good Laboratory Practice ✓

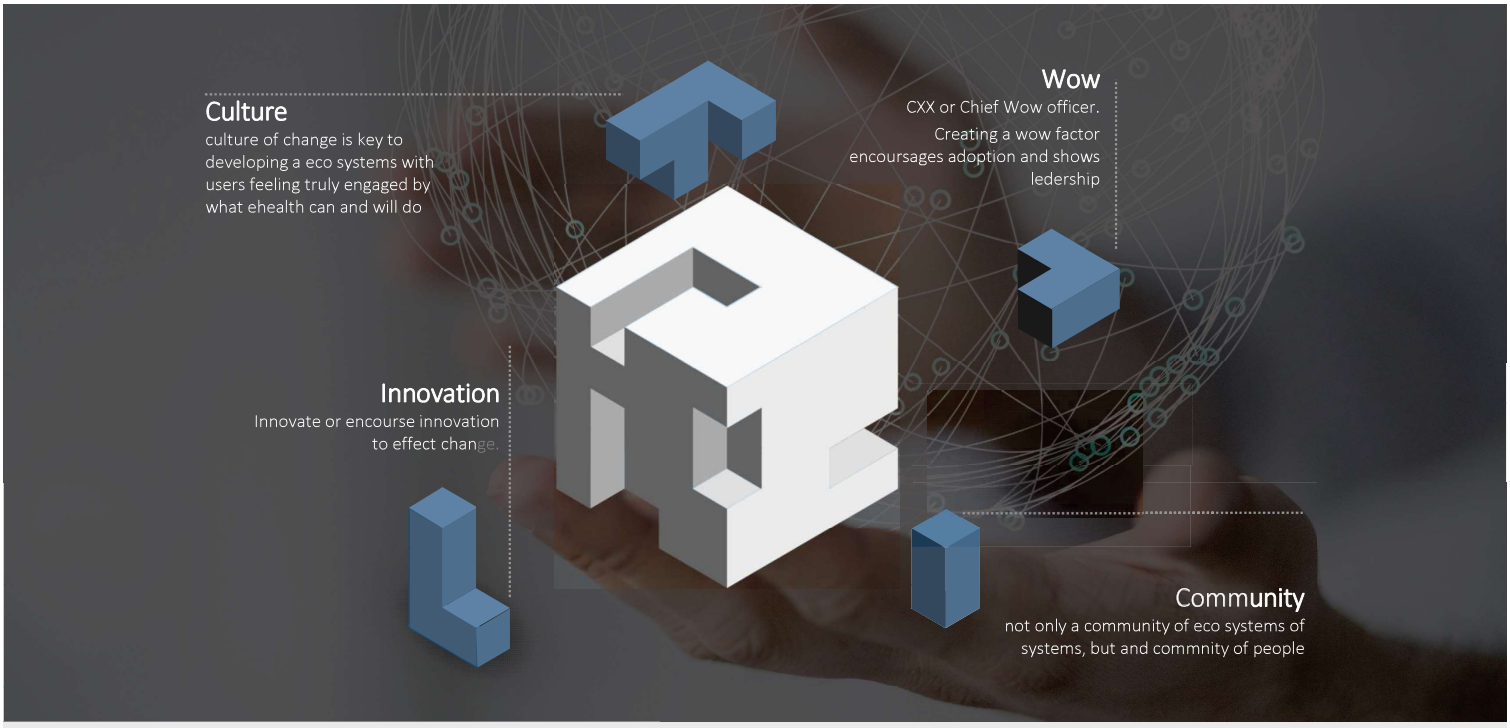
☐ ISO 2007

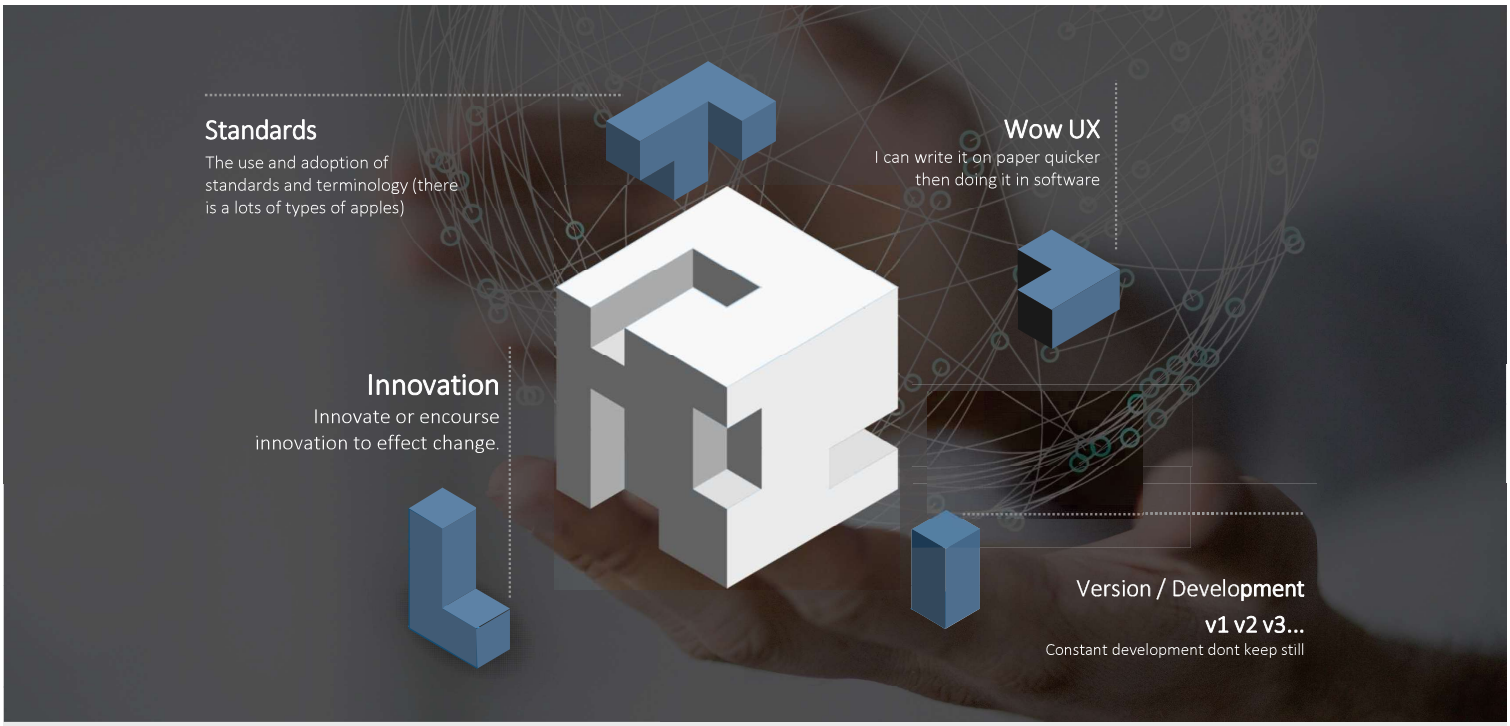
☐ ISO 9001

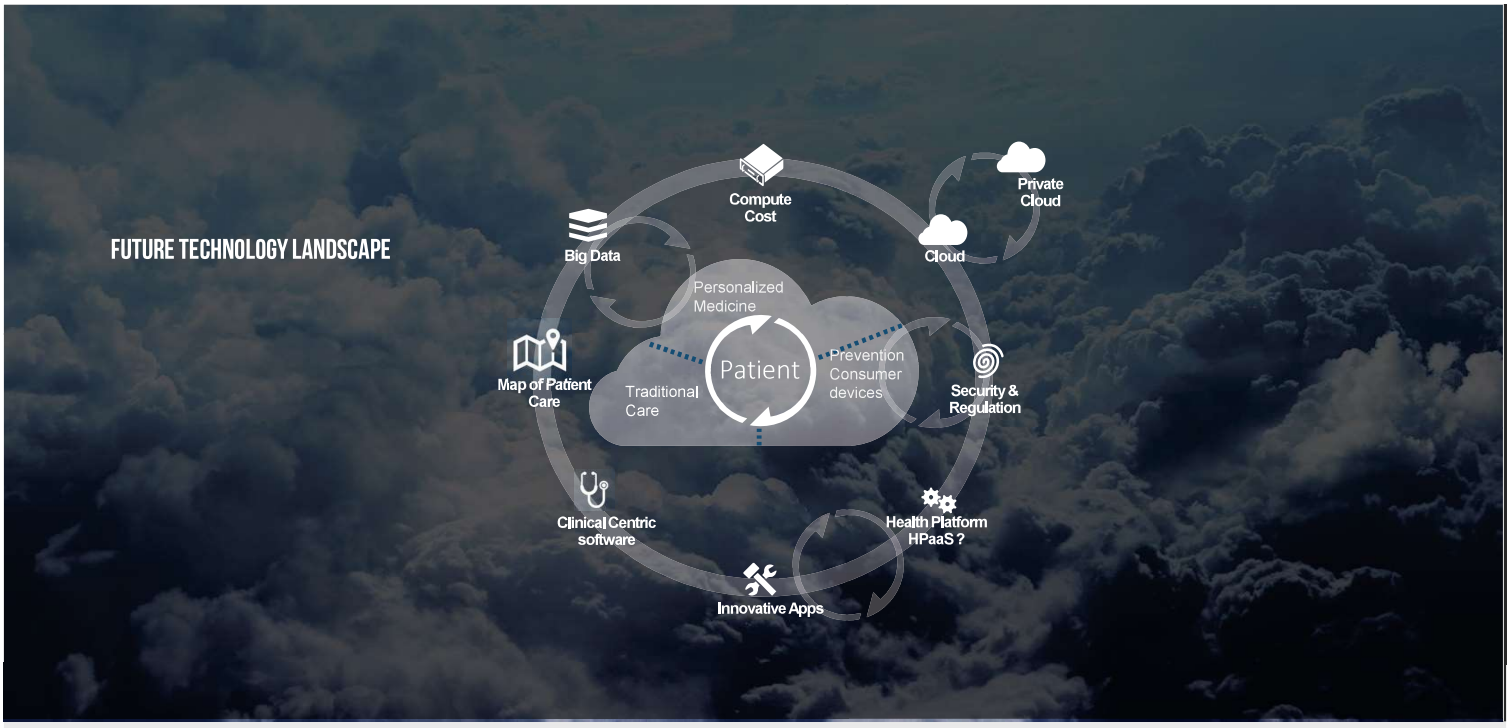
☐ ECRIN Data Centers

☐ FDA CRF 21 Part 11


FUTURE


Culture
culture of change is key to developing a eco systems with users feeling truly engaged by what ehealth can and will do
Wow
CXX or Chief Wow officer.
Creating a wow factor encoursages adoption and shows ledership
Innovation
Innovate or encourse innovation to effect change.
Community
not only a community of eco systems of systems, but and commnity of people


Standards
The use and adoption of standards and terminology (there is a lots of types of apples)
Wow UX
I can write it on paper quicker then doing it in software
Innovation
Innovate or encourse innovation to effect change.
Version / Development
v1 v2 v3...
Constant development dont keep still


FUTURE TECHNOLOGY LANDSCAPE
Compute Cost
Private Cloud
Big Data
Cloud
Personalized Medicine
Patient
Map of Patient Care
Traditional Care
Prevention Consumer devices
Security & Regulation
Clinical Centric software
Health Platform HPaaS ?
Innovative Apps


## FUTURE TECHNOLOGY LANDSCAPE

### NEW HIGH-TECH INFORMATION TECHNOLOGIES FOR BETTER CARE

We have to start adopting new technology within the NHS that is clinical focused

### SECURE INFORMATION & COMMUNICATIONS TECHNOLOGY (ICT) SYSTEMS

We need to have systems that the public trust when it comes to sharing data and genomics

### CLINICAL APPLICATIONS

Clinical systems that really are clinical or cover specialties will be the only way we can get the data we need

### INNOVATION

We need to innovate to make all of this happen and we all have to play a part in this

# QUESTIONS?