IMS Health & Quintiles are now IQVIA®

Life after Brexit-UK Life Sciences as a global power house

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Market Development Director

September 2019

We support the Life Sciences across 8 key areas in the UK

Q² SOLUTIONS

- >9M tests performed per year
- Genomics, precision medicine, bioanalysis & vaccines

R&D SOLUTIONS

- 4 Prime Sites
- >90 hospitals
- 20% of all UK commercial clinical trials
- >7,000 patients in clinical studies from >200 studies

REAL-WORLD INSIGHTS

- >270 Real World Data scientists
- >17M anonymised patient-level records

HEALTHCARE SOLUTIONS

- Services to > 75% of NHS hospitals
- Offerings
  - Benchmarking
  - Patient Level Costing
  - Clinical Coding
  - Patient Experience
  - Audit Management
  - Market Access

INFORMATION OFFERINGS

- 82% of retail pharmacies prescription data
- 98% of hospitals
- 98% of wholesalers distribution sales
- >1bn individual prescriptions transactions per year

COMMERCIAL SERVICES

- Support 19/20 of top pharma
- Primary Intelligence, Commercial Effectiveness, Marketing Services
- Management & Strategy Consulting across the full lifecycle

CONTRACT SALES & MEDICAL SOLUTIONS

- >500 professionals:
  - Healthcare professionals (HCP)
  - Promotional Teams
  - Patient Support, Nursing and Home Care
  - Medical and Patient Communications
  - Medical Affairs & Medical Scientific Liaison (MSL) Teams

TECHNOLOGY SOLUTIONS

- Providing technology solutions to 19/20 top pharma
- Key Provider of managed HCP data with >6,800 users (OneKey)
- >2,000 CRM users

IQVIA provides integrated core-enabled offerings to support the life sciences sector, from molecule to market

IQVIA CORE™

Experience our difference. Experience the IQVIA CORE™

Almost everything we do in Human Data Science is powered by the IQVIA CORE. This holistic approach allows us to generate unique perspectives that we use to create solutions for our customers. By infusing the CORE into everything we do, we can help our customers rethink approaches to clinical development and commercialization, reframe old challenges into new opportunities, and reimagine what's possible.

Learn more about how the components of the IQVIA CORE come together to channel the insights, commercial and scientific depth, and executional expertise that drive maximum value for our customers.

Through IQVIA CORE and our strategic collaborations with the NHS and life sciences, we are committed to bring UK Healthcare forward.

Domain Expertise
4,000 employees; 4th largest Life Sciences employer in the UK
100+ Medical Doctors & PhD's, 400+ Masters degrees

Transformative Technology
Leading CRM provider for Life Sciences, Real World Technology platform E360™

Unparalleled Data
98% hospital Rx data, 82% retail Rx data, 16M patient lives through Medical Research Data

Advanced Analytics
Real World Evidence, Analytics Center of Excellence and advanced analytics hubs powered by advanced Machine Learning and Artificial Intelligence techniques

IMS Health & Quintiles are now

Brexit-Gearing to Attract Research and Launch medicines

EU Medicines & Clinical Trial Law translated into UK Law on Exit Day

Statutory Instruments

Transposed legislation

- Direct translation of EU law into UK law replacing reference to EU bodies
- Amending Regulations will come into force on exit day in case of no deal

2001/83/EC and amending legislation (Medicines Directive)
2001/20/EC and amending legislation (Clinical Trials)
Medical Devices Regulation (EU) 745/2017
In-vitro Diagnostic Devices Regulation (EU) 746/2017

Amendments

Medicines and Devices

The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019
The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019
The Human Medicines (Amendment etc.) (EU Exit) (No. 2)
The Medical Devices (Amendment etc.) (EU Exit) (No. 2) Regulations 2019

Amending -
Human Medicines Regulations 2012
Medicines (Fees) Regulations 2016
Medical Devices Regulations 2002

Clinical Trials

The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019
Amending -
Medicines for Human Use (Clinical Trials) Regulations 2004

Clinical Trials submissions portal live from Exit Day

Clinical trials

- Future regulatory divergence
- Risk of IMP delivery delay
- Leaving EUDRACT

CTs submissions

- National competency, **not impacted**
- **UK portal live by exit** day; as the new EU portal for the updated CTR
- EU and UK already accept data from multi-national trials

CTs transparency

- Transparency measures will be strengthened under the new EU Clinical Trials Regulation (CTR) 536/2014. This won't be incorporated into UK law but UK will **align where possible** without delay
- In the short term, UK will continue to use established international registers EudraCT (EU), ISRCTN (UK), ClinicalTrials.gov (USA)

CTs amendments

- CTs will need **a legal representative / sponsor in UK or approved country** (EU/EEA)
- **EU release site in addition to UK**, duplication of QP role
- Country on the approved country list (includes EU/EEA) can directly supply material to UK trials
- 1 year transition period: **MIA (IMP) Import authorisation required**, overseen by QP, substantial amendment

Commercial launch

- Loss of commercial interest due to duplication of regulatory burden[1], price increase and market access delay (affecting returns[2] and launch sequence[3])
- UK not a decision maker at EU level

MHRA will take on all EMA assessments from Brexit day. Orphan designations will be UK converted. New incentives for RD indications

Market authorisation

Alignment to EU timelines & guidelines + MHRA to build on CHMP's assessment reports

Marketing Authorisation Grandfathering	• UK-based MAHs for CAPs, MRP, DCP have been transferred to EEA-based entities • **MHRA**: **all existing MAs will be automatically converted** to UK MAs on exit day, no fee • For ongoing applications (CAPs, MRPs, DCPs, variations, etc), the MHRA will take on the EMA/HMA's assessments, only requiring a parallel submission if the process is in early stage (e.g. DCP before day 70).
New MHRA submission portal	• Will be **ready by exit day** (in pilot state at the moment) • To substitute current EMA portals for MAAs, periodic safety update reports (PSURs), paediatric investigation plans (PIPs), clinical trial applications, qualified person for pharmacovigilance (QPPV) and pharmacovigilance system master file (PSMF) notifications, etc.
Orphan drugs	• **Current designations will be UK converted** • Current **EMA OD requirements will be maintained** • **UK will offer incentives** in the form of market exclusivity (10+2y) and full or partial refunds for marketing authorisation fees to encourage the development of medicines in rare diseases.
ATMPs	• **Same principles** on data, licensing, packaging, etc **will continue to apply** • Definitions of individual classes of ATMPs will remain unchanged • However new ATMPs classifications in the UK will be undertaken by the MHRA in accordance with the legislation and current guidance and may vary from the EMA's
Legal presence	• Need to establish a **legal presence in the UK before the end of 2020**

MHRA accelerated pathway-opinion in <150 days

Clinical trials

- Future regulatory divergence
- Risk of IMP delivery delay
- Leaving EUDRACT

Market authorisation

- Need to transfer UK MA to EEA MA & duplicate to national UK MAs (CAPs, MRPs, DCPs)
- Need to transfer UK MAH to EEA legal entities
- Impossibility of submitting both MHRA & CMA applications during transition period
- Developing new national processes for CAPs, variations & designations (OD, PD, ATMP, IMPs)

Man… & b…

An opportunity to accelerate the market access for innovative medicines

New fast track assessments

Accelerated Assessment Pathway

- Enhancing availability of novel medicines: New active substances, biologicals, orphans, conditional and exceptional circumstances
- MHRA opinion <150 days

Rolling Review pathway

- New route for MAA intended to enhance the development of novel medicines
- On-going regulatory input & feedback enabling; phased approach to evaluation
- Available for all products containing new active substances, including biologicals

Building on existing UK innovative initiatives

NICE National Institute for Health and Care Excellence

EAMS

MHRA Innovation Office

MHRA Regulating Medicines and Medical Devices

Accelerated Access

HTA Human Tissue Authority

The regulatory advice service for regenerative medicine (RASRM)

NHS Health Research Authority

Human Fertilisation & Embryology Authority

The Government has identified and developed solutions to address the key risk areas for the Life Sciences

Medicines supply to UK & EU remains at significant risk

The Govt contingency plan has focused on 4 key areas

1. Securing alternative transport routes

- DHSC confirmed **medicines will be prioritised** at the borders
- DHSC has set up a **dedicated shipments channel** for medicines/devices in Belgium to secure a 3 day turn-around & **additional ferry capacity** for medicines (new routes will be Felixstowe, Poole, Plymouth, Portsmouth to Cuxhaven Germany, NL, Caen, Cherbourg, Brittany).
- The DHSC will secure an '**express freight service**' to transport small medical supplies within 24h.
- Additional plans are being put in place for a **freight capacity framework agreement** that will provide the ability to secure freight capacity for critical supply chains when required. Medical products will be prioritised.

The ask to industry is to secure additional transport capacity via any of the facilitated routes described above.

Distribution

- Supply chain delays: 90% of medicines in and out of UK go through the Port of Dover. If no deal is agreed, the Dover-Calais route could run at only 12-25% of normal capacity for up to six months
- New levies and custom tariffs
- Parallel export / import affected

2. Increasing product stocks

- The Government will continue **providing additional warehouse** space for stockpiled medicines, including ambient, refrigerated and controlled drug storage.

The ask to industry is to commit to a minimum of 6 weeks additional stock via private or Government-facilitated storage.

3. Addressing medicines shortages

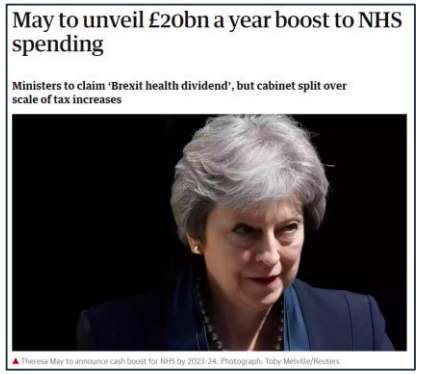
- A **National Supply and Disruption Response (NSDR)** unit will be set to enable **ministers to issue serious shortage protocols** to pharmacists.
- A serious shortage protocol (SSP) was agreed to give **pharmacists** additional powers to **alter prescriptions** in the event of a serious shortage of a particular medicine

4. Supporting trade readiness

- The Govt is working with industry to improve trader readiness in preparation for the new customs procedures
- Further **clarification on regulatory requirements** will be communicated with industry via ABPI and webinars

designations (OD, PD, ATMP, IMPs)

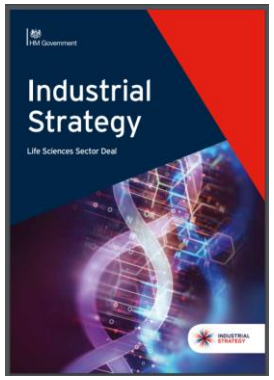
BREXIT has been a catalyst for UK Government's to bring about policy change to improve the environment for Pharma, biotech and wider life sciences


May to unveil £20bn a year boost to NHS spending

Ministers to claim 'Brexit health dividend', but cabinet split over scale of tax increases

Theresa May to announce cash boost for NHS by 2023-24. Photograph: Toby Melville/Reuters

- June 2018: Theresa May announces an extra £20bn a year for the NHS
- Life Sciences Industrial Strategy recommends UK spends to move into top quartile of OECD innovation uptake by 2025 (£1bn/yr uplift)



- **Life Sciences Industrial Strategy**
- Two Life Sciences Sector Deals 2017 and December 2018
- Blueprint for investment by Government and the private sector-highlights to enhance UK for Life Sciences.
- Increased investment in R&D to £12.5bn by 2021, accelerating clinical trial recruitment & building a more attractive clinical trial environment

- 8.10.18: NIHR & IAOCR *High Throughput Clinical Research* in NHS in response to LSIS goal to increase the number of clinical trials conducted in the UK over the next 5 years by 50%
- They aim to make the UK a country of 1st choice for the conduct of clinical trials through a combination of initiatives which result in trials being set up and conducted efficiently and effectively in 'high throughput centres'

The Foundations for the UK to become a Global Life Sciences Power House Post Brexit?

1

The UK's Unique Rich Health Data Eco-System

Single NHS payer system with unique patient number & longitudinal health records; UK leading the world in RWE studies; Opportunity to scale research activity by using unique health care data

2

A World Leading Genomics Strategy

1st country in world to sequence 100,000 genomes.Genomics England & IQVIA collaboration to integrate GEL database with IQVIA's UK clinical trials capabilities.

UK Biobank 500,000 whole genomes.

3

New Strategies to Optimise the UK Clinical Trials & RWE Environment

NIHR Leadership;HRA speeding up trials approval process; NHSE implementing 12 Actions to Improve Clinical Research; Digital Recruitment; New approaches to Real World Data and Clinical Trial Protocols

4

UK Pharma Productivity

Pharma has highest productivity index of any UK industrial sector, including IT and finance.

5

Government Policy

Life Sciences Industrial Strategy

1st and 2nd Life Sciences Sector Deal;

NHS E Supporting Research in the NHS;

NHS Digital Health Strategy

6

Initiatives to Improve UK Patient Access

LSSD Target UK in Upper Quartile of OECD average for innovation uptake by 2025; the new Voluntary Pricing Access Scheme-focus on innovation uptake; MHRA scaling up for faster approvals post-Brexit; NICE, Industry and NHSE collaboration on pricing schemes; Accelerated Access Collaborative Progress;

Leaders who are changing the dynamic for UK life sciences….

Ministers and policy makers making a difference to UK Pharma and Life Sciences environment

Matt Hancock
SoS for Health & Social Care

Baroness Nicola Blackwood
Parliamentary Under-Secretary of State for Health

Lord David Prior
Chair NHSE

Lord Ara Darzi
Chair of Surgery at Imperial College London

Professor Sir John Bell
Architect Life Sciences Industrial Strategy

Simon Stevens
Chief Executive NHSE & I

Matthew Gould
CEO NHSX

Blake Dark
Commercial Medicines Director, NHSE

Dr Sam Roberts
CEO Accelerated Access Collaborative

Tamsin Berry
Office for Life Sciences

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Government and LS Sector Industrial Strategy(LSIS) & Deals to support UK life sciences

LSIS : Establish the UK as the world's most innovative life sciences economy

R&D Investment 2017-2027 will strengthen UK Clinical Research Environment

1 Raise the intensity of research and development (R&D) in the UK

Increase investment in R&D to **2.4%** of GDP by 2027 and **3%** over the longer term, delivering an estimated increase of **£80bn** over the next 10 years

Increase in R&D investment of **£2.3bn** in 2021/22, raising total public investment from around £9.5bn in 2016/17 to **£12.5bn** in 2021/22, thus increasing the total support for R&D by a third

Increase in the rate of the R&D expenditure credit from 11% to 12% with effect from 1 January 2018

2 Strengthen the environment for clinical trials

The government, through the National Institute for Health Research, has invested significantly, with a new contracts worth more than £950m over the five years from April 2017

NHSE, NIHR & HRA speed up clinical trial approvals & recruitment through the the 12 Actions to Support and apply research in the NHS for clinical trials

Creation of National Bio Resource for Translational Research in Common and Rare Diseases enables people to participate in early translational research and links closely with the UK's 100,000 Genomes Project

LSIS : Establish the UK as the world's most innovative life sciences economy

3

World Leader in Genomics & Development of Precision Medicines

1st country in world to sequence 100,000 genomes 2018
UK Biobank to sequence 500,000 whole genomes by 2025.
Genomics England & IQVIA collaboration to integrate GEL database with IQVIA's UK clinical trials capabilities.

Creation of National Bio Resource for Translational Research in Common and Rare Diseases enables people to participate in early translational research and connects with the UK's 100,000 Genomes Project

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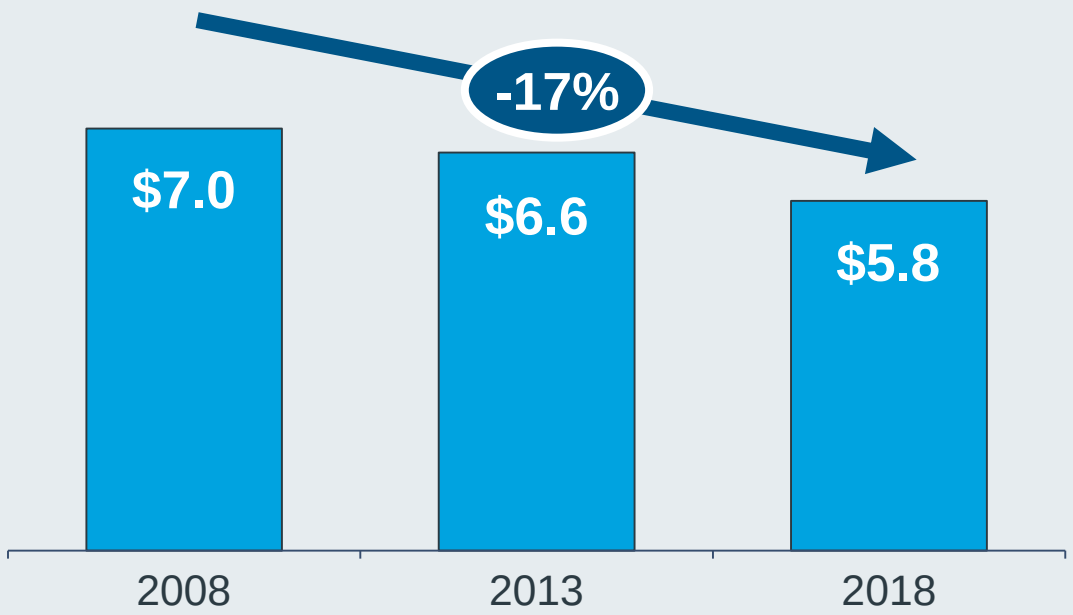
Pillar 1-the health of clinical research in the UK since Brexit

Globally RoI on R&D is declining

Increase in R&D costs is a major issue for pharma, but better is possible

Industry Return on R&D Investment^

(Profit per $1 of R&D spend)



4.8 years
to an accurate diagnosis for rare diseases

~80%
of clinical trials are delayed by at least 2-3 months

+$1B
increase in cost to bring an asset to market vs 2013

~45%
of protocol delays could be avoided through better use of data

^ Top 25 Innovator Pharma companies Source: Company Financial Reports; IQVIA Analysis

The UK is aligned to future clinical trial needs

6
of the global top 20 leading medical universities

21%
growth in number of clinical trials* across the UK

~20%
higher chance of access where a submission includes RWE within the UK

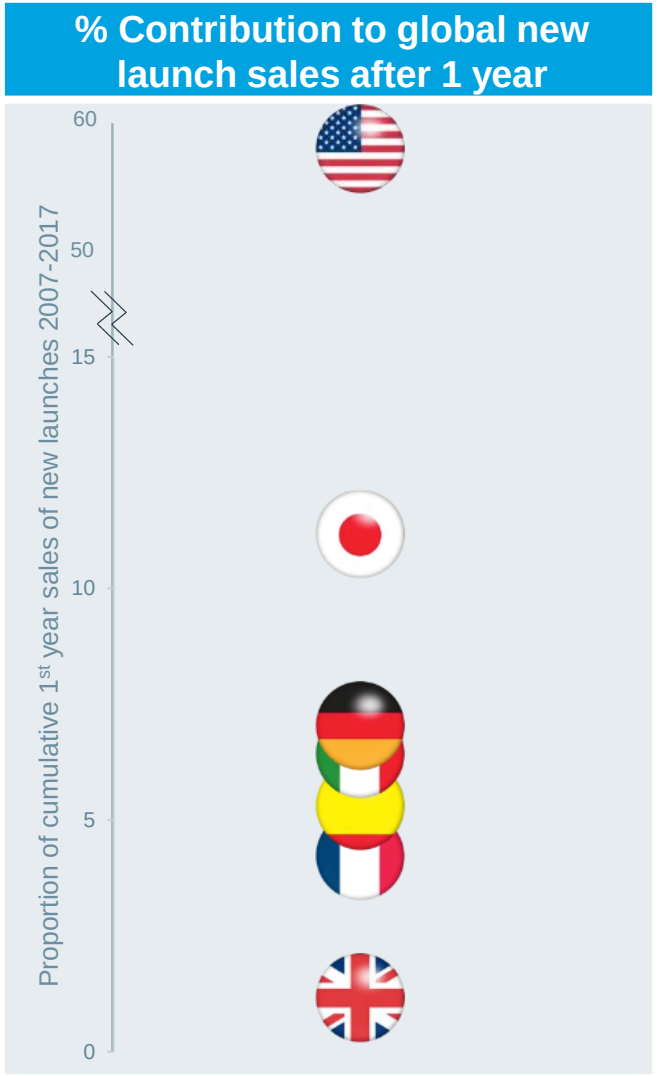
45%
FDA approvals over the next 5 years will be for orphan diseases

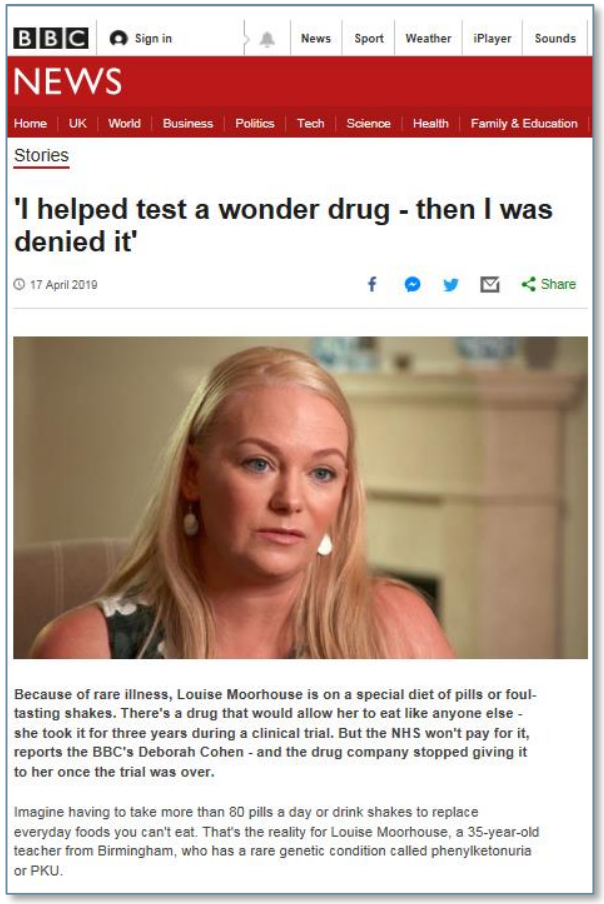
Drugs in trials for orphan diseases (EU markets)

282
products in active clinical trials in UK currently orphan designated
(#1 rank in Europe, +8%)

* IQVIA Clinical Trials

However, the UK has challenges it must address

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Stories

'I helped test a wonder drug - then I was denied it'

17 April 2019 Share

Because of rare illness, Louise Moorhouse is on a special diet of pills or foul-tasting shakes. There's a drug that would allow her to eat like anyone else - she took it for three years during a clinical trial. But the NHS won't pay for it, reports the BBC's Deborah Cohen - and the drug company stopped giving it to her once the trial was over.

Imagine having to take more than 80 pills a day or drink shakes to replace everyday foods you can't eat. That's the reality for Louise Moorhouse, a 35-year-old teacher from Birmingham, who has a rare genetic condition called phenylketonuria or PKU.

x4
slower start up time in the UK vs US

85
different ethics committees to coordinate

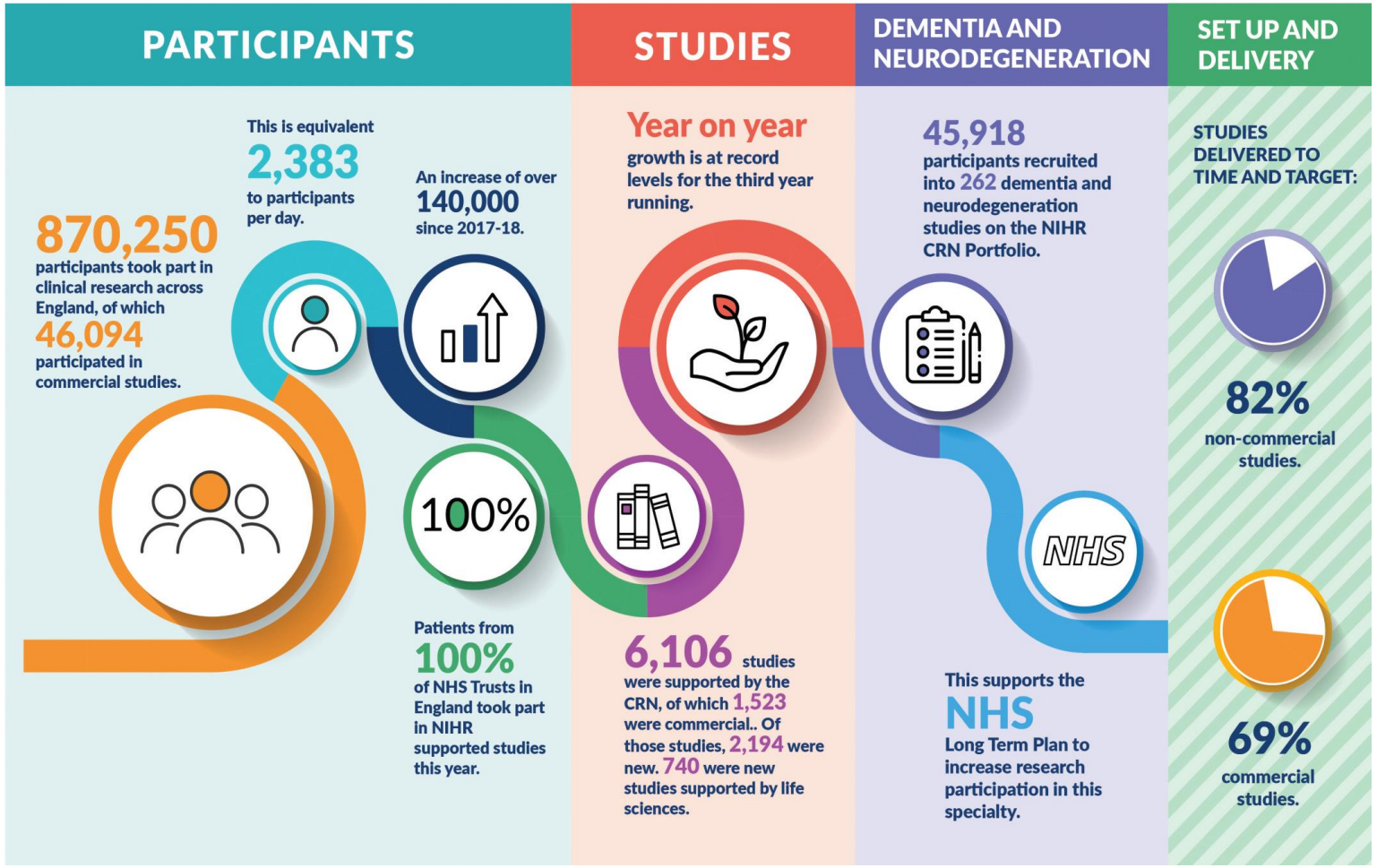
100's
patients each year potentially missing out on participation in clinical trials

x1.9
longer from EMA approval to NICE implementation vs 2014

Source: IQVIA European Thought Leadership, MIDAS LC US $ Q1 2007-Q1 2018.

Clinical research – a key indicator of the health of life sciences in any country

NIHR 2018-9 'The number of participants involved in clinical trials the highest since records began'



- *870K people took part in NIHR clinical studies a 20% increase since 2017/18*
- *Year on year growth is at record levels for 3rd year running.*
- *2018/19, the number of new commercial studies set up across the year was the highest yet - 740 new studies sponsored by the life sciences industry*
- *A record number of 480 cancer studies been added to the CRN portfolio (408*
- *Record number of ongoing studies open for recruitment (1167).*
- *Dementia and neurodegeneration research (DeNDRoN) saw a 26% increase in year with a record number(93) new studies added to its portfolio*
- *Significant increase in people accessing research opportunities 2018/9 compared 2017/8 - up by 20%*

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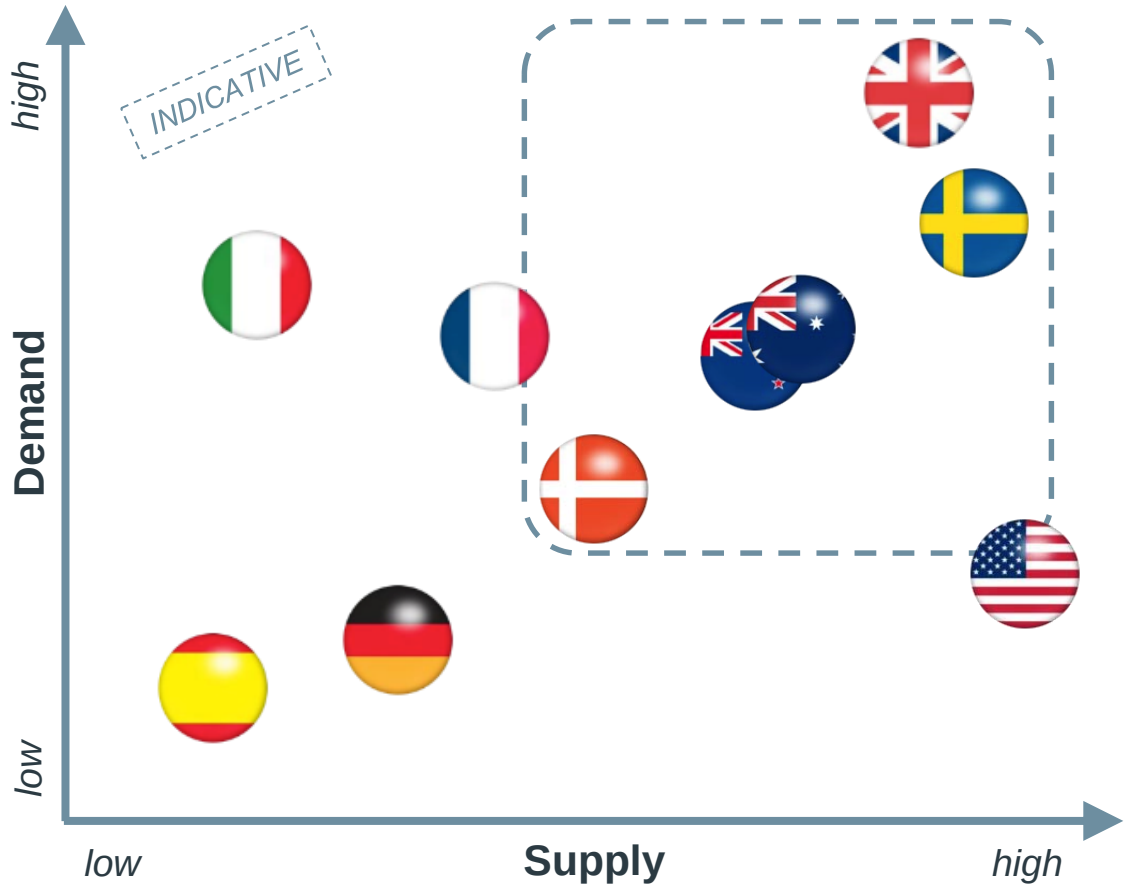
Pillar 2: UK leading the world in use of Real world studies and their application for HTAS and Value Stories

The UK is one of the world leaders in Real World Evidence in both demand and supply

RWE supply & demand landscape

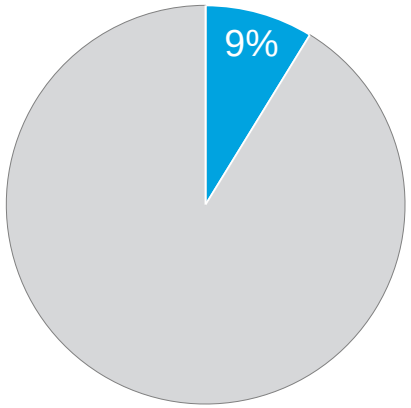


- Supply: type and quality of RWE assets, eg breadth/depth of data, ability to link etc. UK and Sweden score high-as does US- its wealth of commercially available, large data sets
- Demand: the extent to which RWE is accepted by HTA bodies and payers to influence decisions.

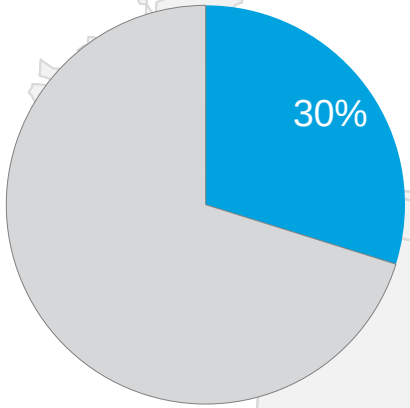
RWE will help the LSIS Goal of the UK being in the upper quartile of the OECD average for uptake of innovative medicines by 2023

NICE Positive Approvals have global impact – the fact that RWE increases launch success by +20% in UK will attract further UK launches and RW Studies

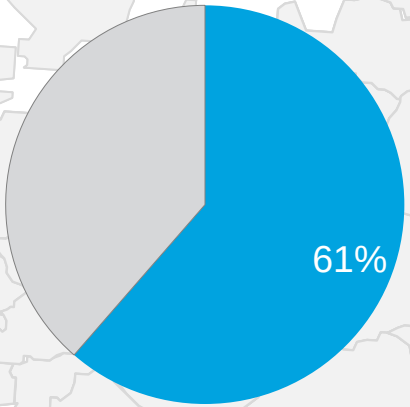
Rejected despite RWE



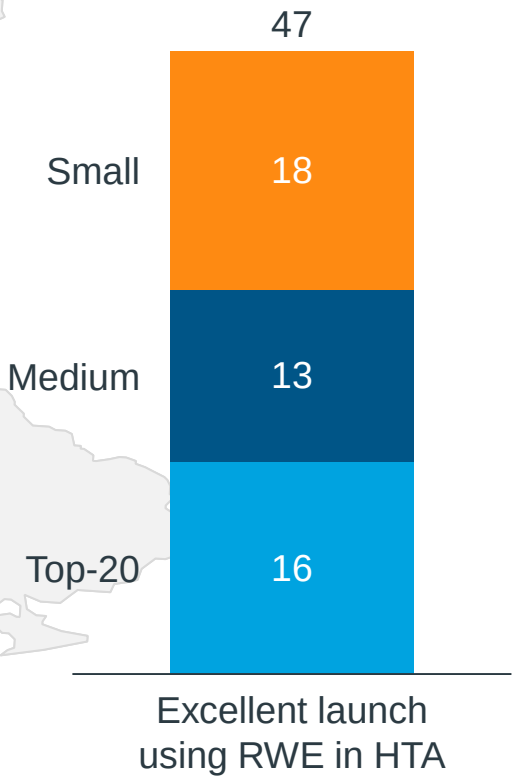
Positive with restrictions and RWE submission



…positive recommendation and RWE submission



Launch excellence



Excellent launch using RWE in HTA

ORPHAN MEDICINES LAUNCH EXCELLENCE Sustaining launch success as Orphan Medicines come of age (March 2019)
Company size based on MIDAS Q4 MAT total sales 2018; Medium = >Top-20 <Top-50; Small = other, plus universities and academic institutions; HTA Accelerator analyses (April 2019)

NICE are proposing to utilise broader sources of data and analytics to inform their decision making and guidance

NICE remit

Develop recommendations, advice and information through a diverse range of programmes to help the health and social care system to deliver the best outcomes for people using services with the resources available within the NHS

Purpose of this consultation

NICE wants to use broader sources of data and analytic methods to enhance their existing methods and processes and inform future guidance

Sources of data NICE are proposing to use

- A wide range of data sources are available for use and will depend on the review question
- Sources of data that NICE has already used or could consider using in the future include, but is not limited to:
  - Primary care and secondary care databases
  - Registries which collect data on how particular treatments are used
  - Surveys of people using health and social care services
  - Data collected on national trends (e.g. prevalence data)

NICE have identified a number of circumstances in which more extensive use of data could improve their methods and processes

When and why should these data types be used

- Situations where additional data or analysis could be used include, but is not limited to:
  - Where an evidence gap has been identified
  - To measure the effectiveness and cost-effectiveness of interventions in real-world settings
  - To demonstrate comparative effectiveness when the RCT comparator does not reflect real world practice
  - To monitor and evaluate intermediate outcomes of intervention
  - To establish the characteristics of the population of interest in practice
  - To improve tracking of guidance implementation, uptake and impact
  - To update guidance more efficiently than is currently done

NICE anticipates that these proposed changes will help improve their guidance, expedite updates on previously published guidance, and enhance understanding of the impact their guidance has on patients accessing health and social care services

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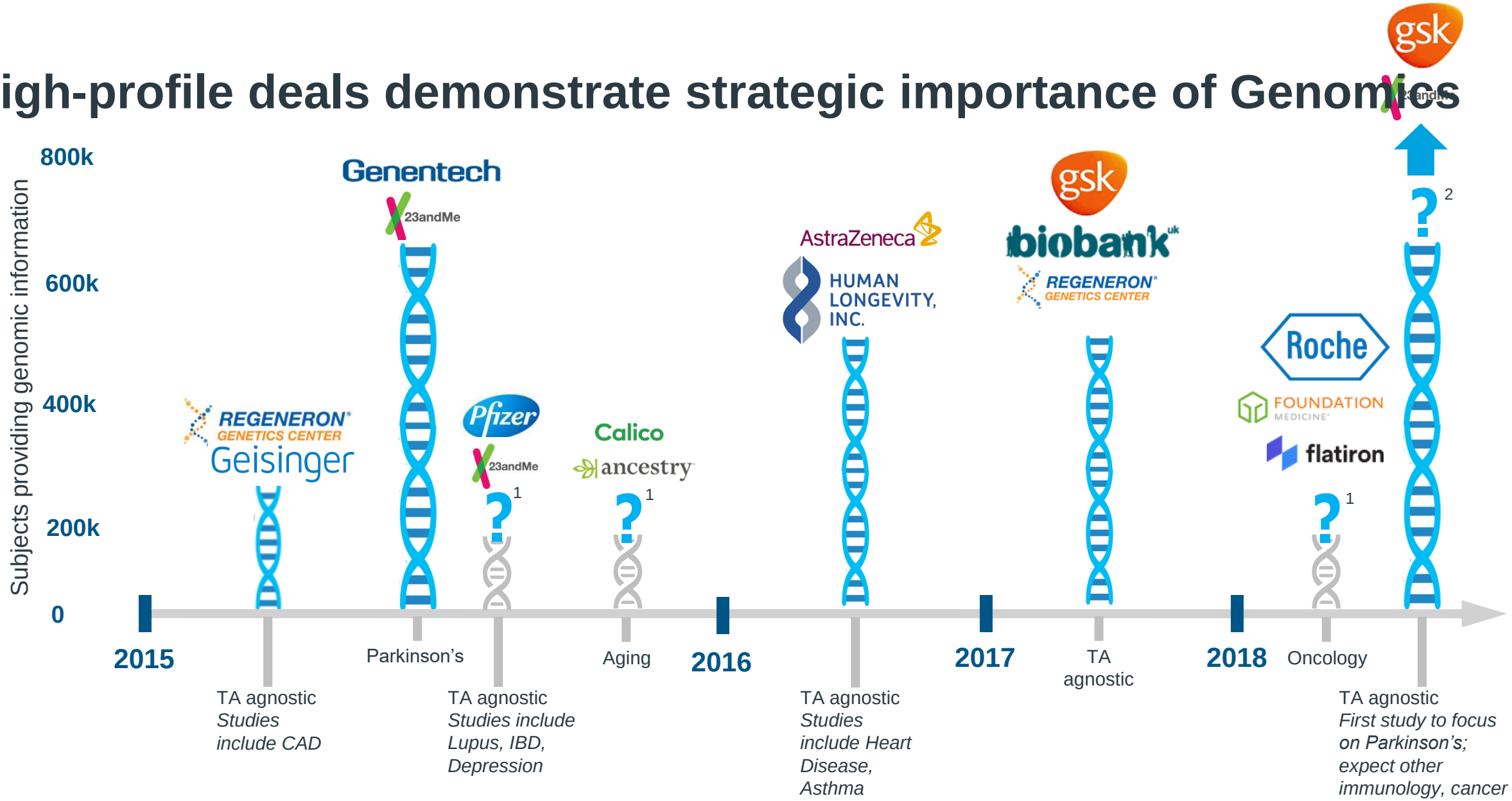
Pillar 3; Genomics

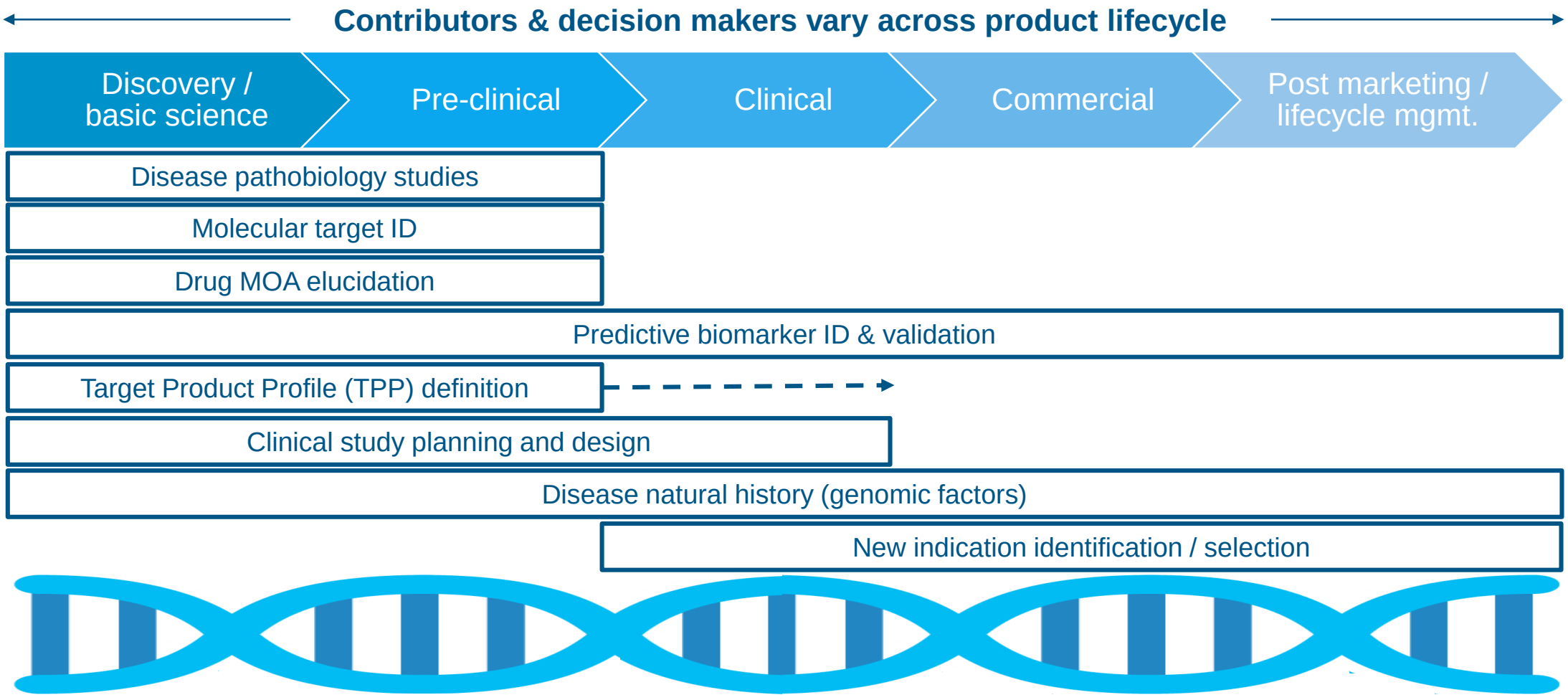
High-profile deals demonstrate strategic importance of Genomics



[1] Pfizer / 23andMe, Calico / Ancestry, and Roche / FMI / Flatiron subject totals not published.

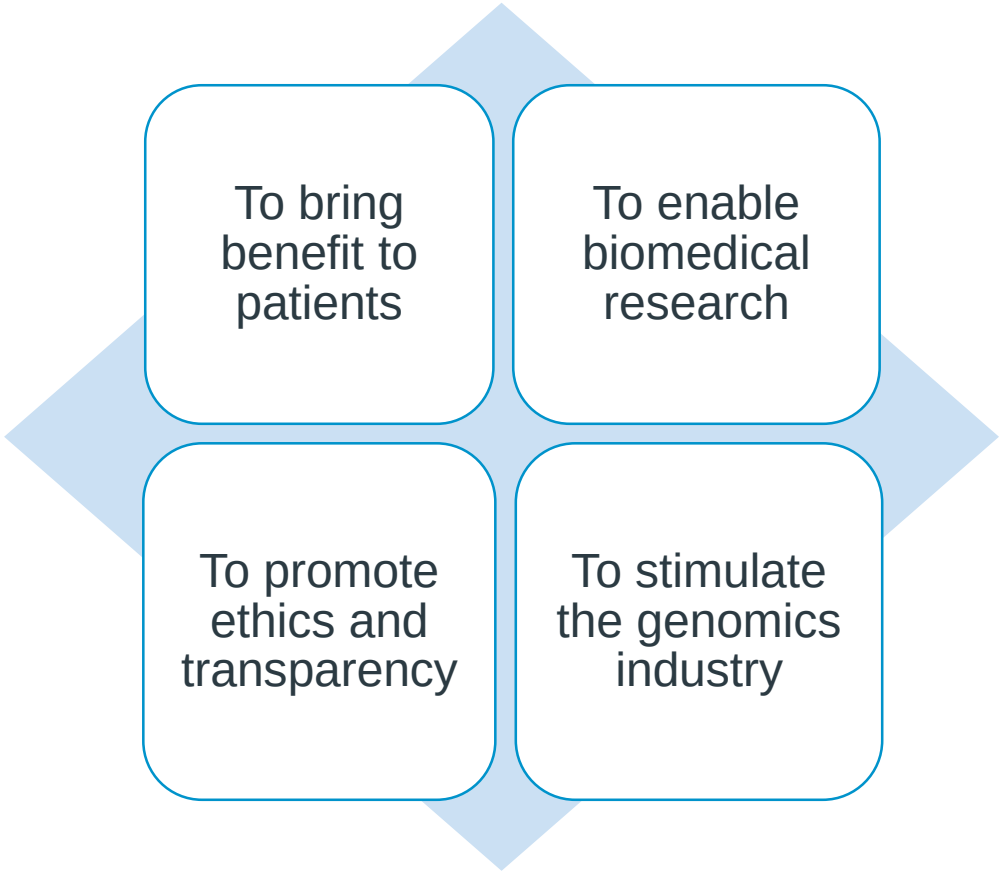
[2] GSK 23andMe has an opt in / opt out model whereby some 80% of the 5 million 23andMe subjects have, by default opted in, but can opt out any time.

And why?
Genomic research applications across the product lifecycle



Principles of the 100,000 Genomes Project

2014-2018

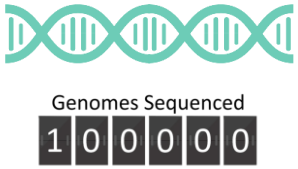


- To sequence 100,000 whole genomes with **rare inherited disease,** and **cancers**
- To return new diagnoses to NHS patients
- To build research infrastructure, capability and skills.
- To generate inward investment
- To lead the world in the application of Genomic Medicine

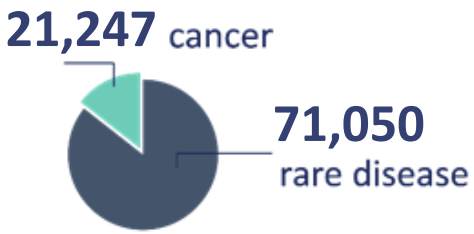
The data value proposition

1

We have a world leading genomics dataset



Genomes sequenced



20-25% actionable findings for Rare Disease

~ 50% cancer cases contain potential for a therapy or a trial in our report

2

It has several applications that can improve health outcomes

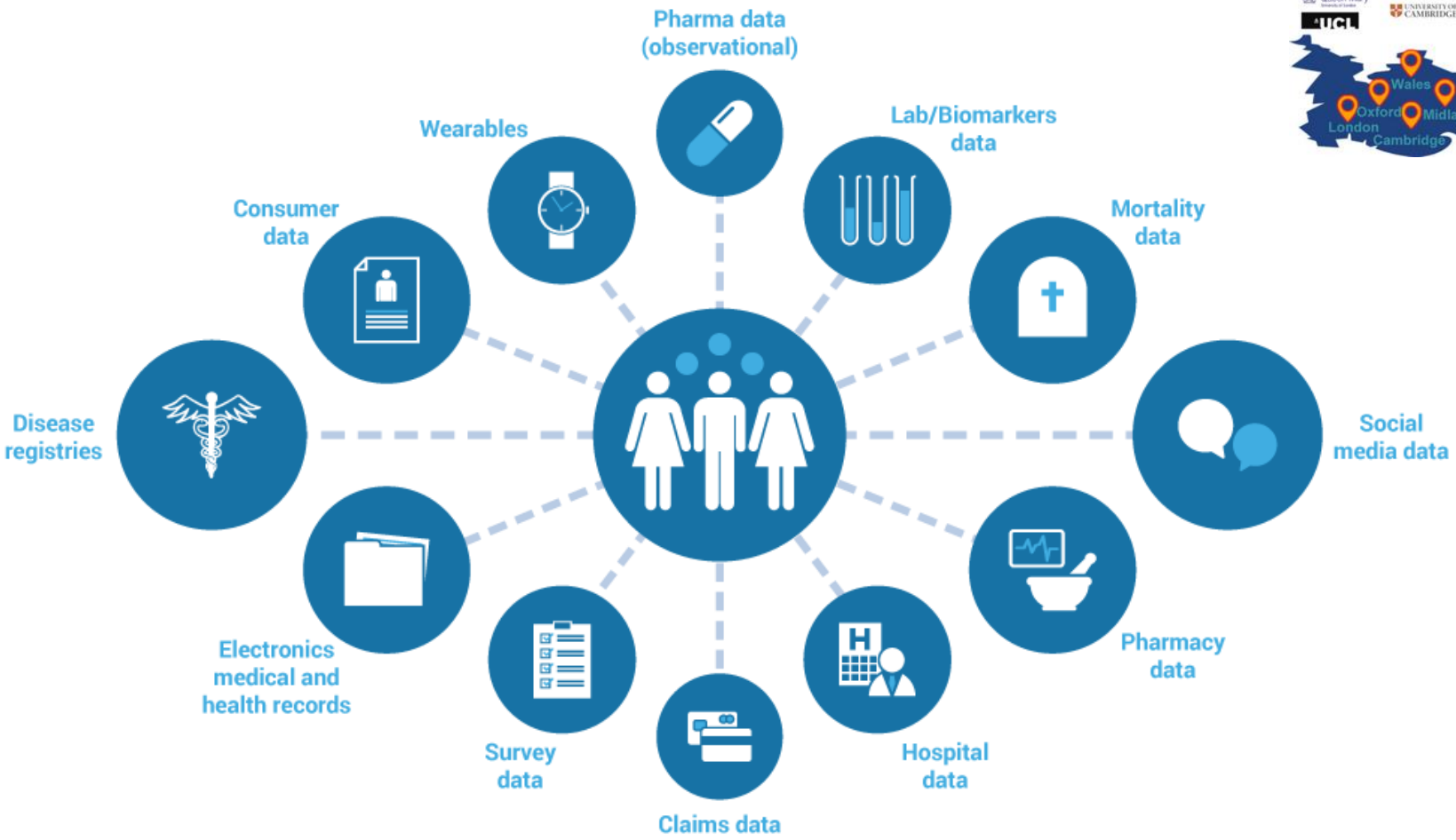
- Stratifying patients
- Better drug development
- Biomarkers design and testing
- Access to samples

3

And has great benefits for all participants

- **Precision trials.** Success case: 30-50% lower cost per trial thanks to better targeting
- **Better analysis of clinical da**ta. Success case: identified 12 patients with homozygous NPHP1 deletions, all previously undiagnosed
- **Safe environment for research through our Research Environment**: allows for data documentation, tools analysis and workflow and collaboration

Access to linked Real World Data



UK Genomics vision announced

Genomic information will become a central platform for precision healthcare in the UK

On the 2nd October, Matt Hancock the Secretary of State for Health and Social Care, announced an ambitious vision for genomic healthcare in the UK…

> Expansion of the 100,000 Genomes Project to **one million whole genomes** sequenced by NHSE and UK Biobank in the next five years

> From 2019, the NHS will offer **whole genome analysis for all seriously ill children with a suspected genetic disorder**, including those with cancer. The NHS will also offer the same for all adults suffering from certain rare diseases or hard to treat cancers

> An **aspiration to sequence 5 million genomes** in the UK within the next five-year years

5 million genomes over 5 years aspiration is system wide

- 500,000 whole genomes through the **Genomic Medicine Service**
- Plus other genomic tests

- 500,000 whole genomes through upgrade of **UK biobank** sequencing

- Whole genome sequencing of **strategic cohorts** (unmet needs and long term value to the healthcare system)

- **Research cohort** sequencing (whole genome and other genomic tests) funded by current and future funding

- Exploratory programme for self-paying **volunteers** who wish to be early adopters of genomic analysis

IQVIA & GeL announced 5 year collaboration to enable Real-World clinical-genomics research and trials in Life Sciences

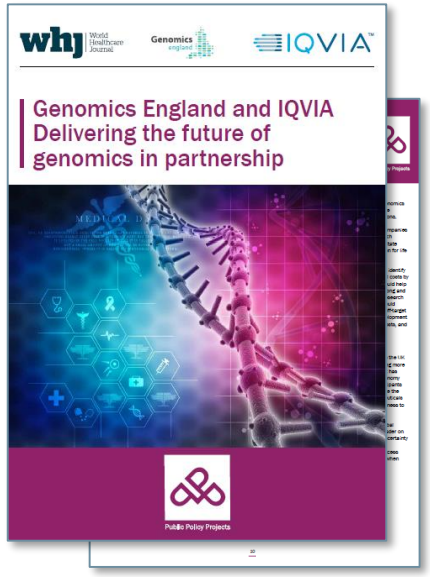
Genomics england

- Genomic data
  - ✓ Genomics expertise
  - ✓ Genomics data and specimen pipeline
- Technology
  - ✓ Genomics data management
  - ✓ Privacy & data governance
- Network
  - ✓ NHS knowledge and connections
  - ✓ Discovery forum
  - ✓ GeCIP
- Genomics development
  - ✓ Data interpretation

Genomic data is a critical element to transform clinical research and healthcare delivery

IQVIA

- Clinical data management
  - ✓ Clinical data models (eg,OMOP)
  - ✓ International data curation & standardization
- Technology
  - ✓ E360™
  - ✓ Privacy Analytics
- Industry engagement
  - ✓ Established customer base
- CRO, trials and network
- Healthcare analytics services to NHS



1 Feasibility Research Data Access Services

Overview
- Access to linked clinical-genomic data via IQVIA's E360 platform for pre-research purposes

Key use cases
- Pre-research use
- Feasibility analysis

2 Analytical Consultancy Services

Overview
- IQVIA provides analytical services using clinical-genomics data

Key use cases
- Clinical-Genomic research

3 Custom Clinical & Genomic Analytical Services

Overview
- Make Genomic testing as part of clinical trials, patients could have their whole genome sequenced in parallel to the clinical trial

Key use cases
- clinical trial undertaken in the UK within precision medicine

E360 REAL-WORLD INSIGHTS

ACoE

Initial services of the IQVIA - GEL collaboration

1

Feasibility Research Data Access Services

Access to linked clinical-genomic data via IQVIA's E360™ platform for pre-research purposes

2

Analytical Consultancy Services

IQVIA provides analytical services using linked clinical-genomics data

3

Custom Clinical & Genomic Analytical Services

Enable genomic testing as part of clinical trials, where patients could have their whole genome sequenced in parallel to the clinical trial

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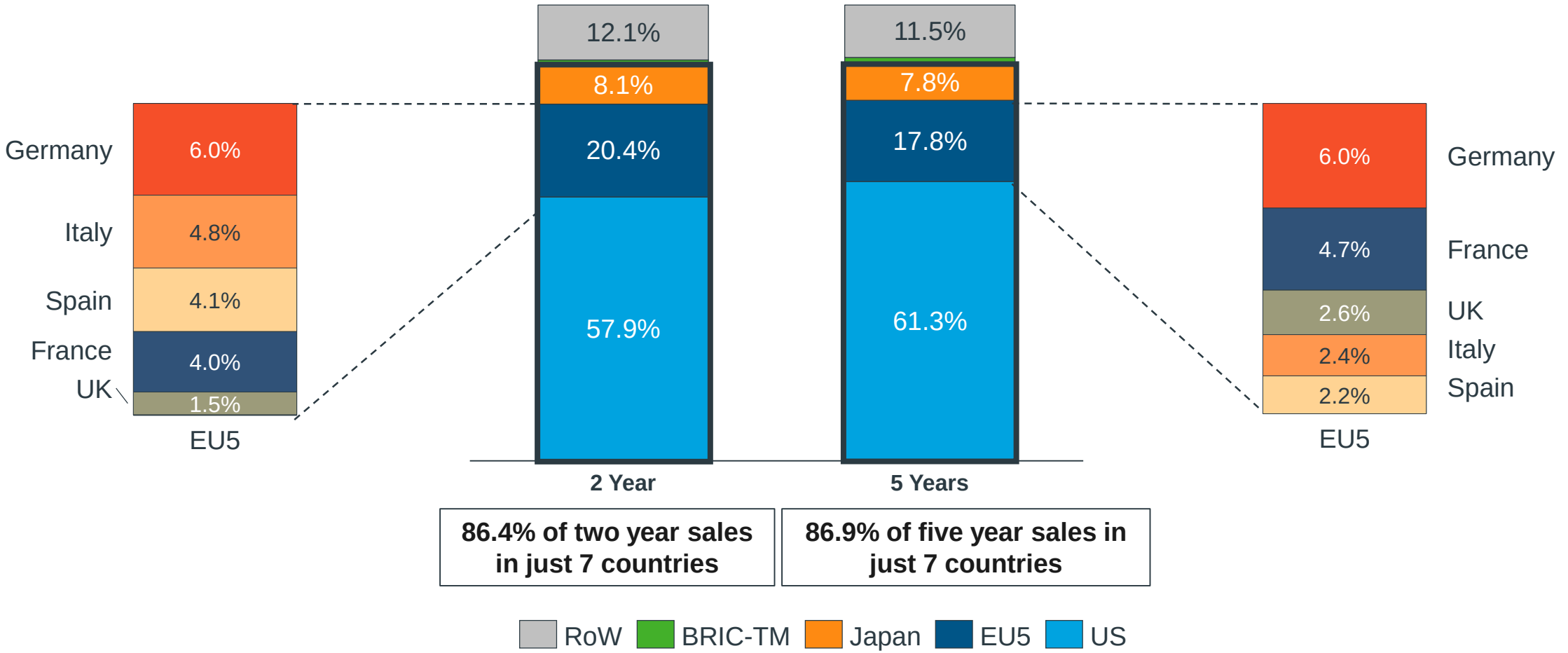
Pillar 4: Access to innovation

UK lowest uptake in EU 5 Yr 1, moving to number 3 in year 5

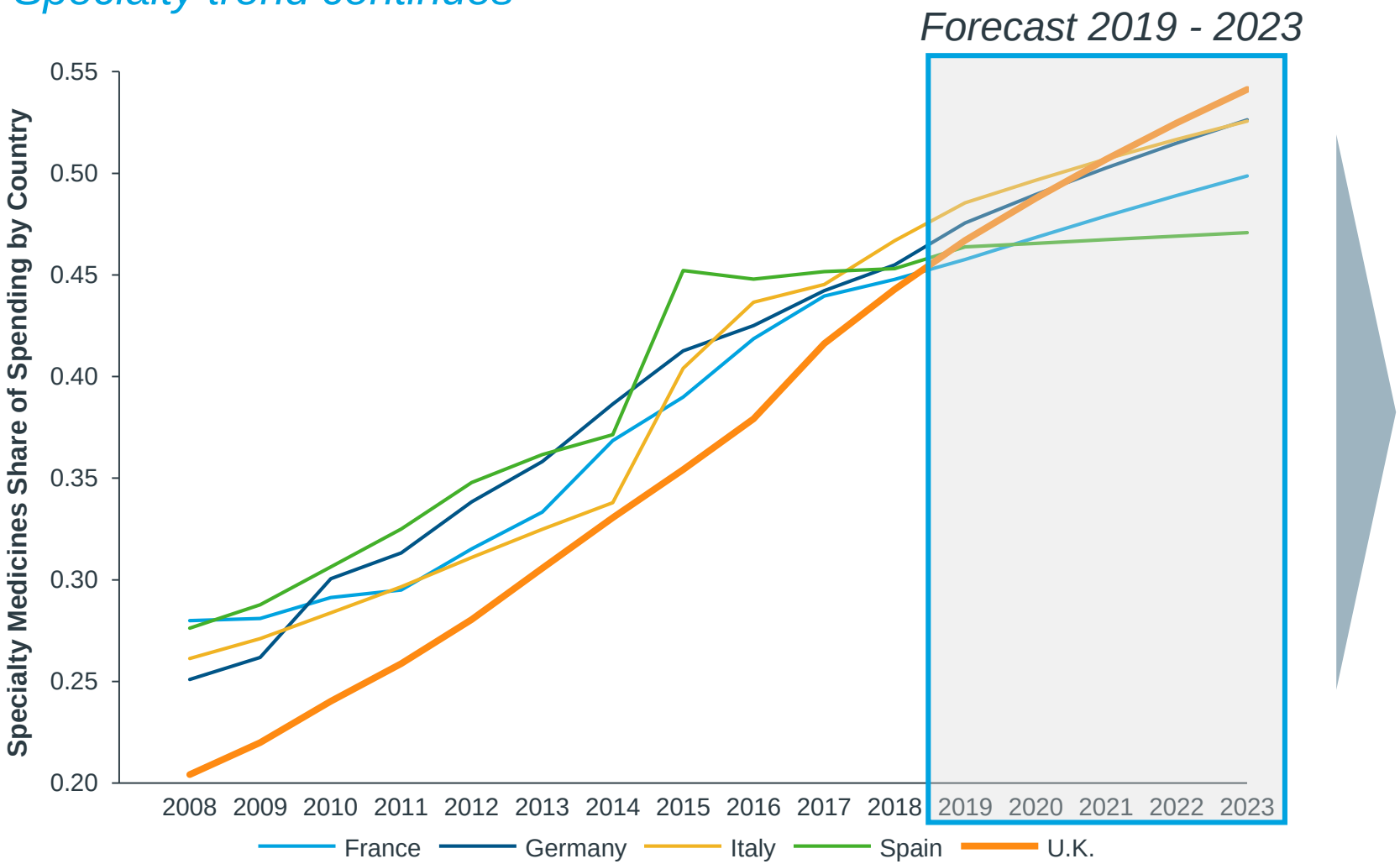
Proportion of cumulative 2- and 5-year sales of new launches 2007-2017 by country



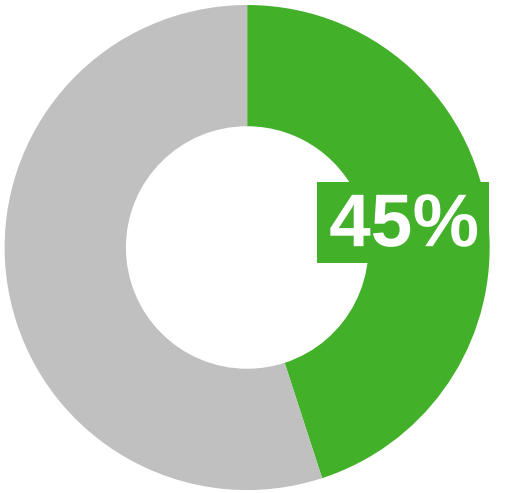
Notes: Country contribution is calculated based on the accumulative sales of NAS (new active substances) launches from 2007 to 2017. Values are pre-rebates and discounts.
Source: IQVIA European Thought Leadership, MIDAS LC US $ Q4 2007-Q4 2018.

Government spend on Specialised Medicines (inc. orphans) across EU5 will continue to be a considerable proportion of new medicines spend

Specialty trend continues



*Orphan forecast of FDA 2019-2023 approvals**



*used as a proxy for future medicines. Note: variations in orphan medicines definitions between US and EU

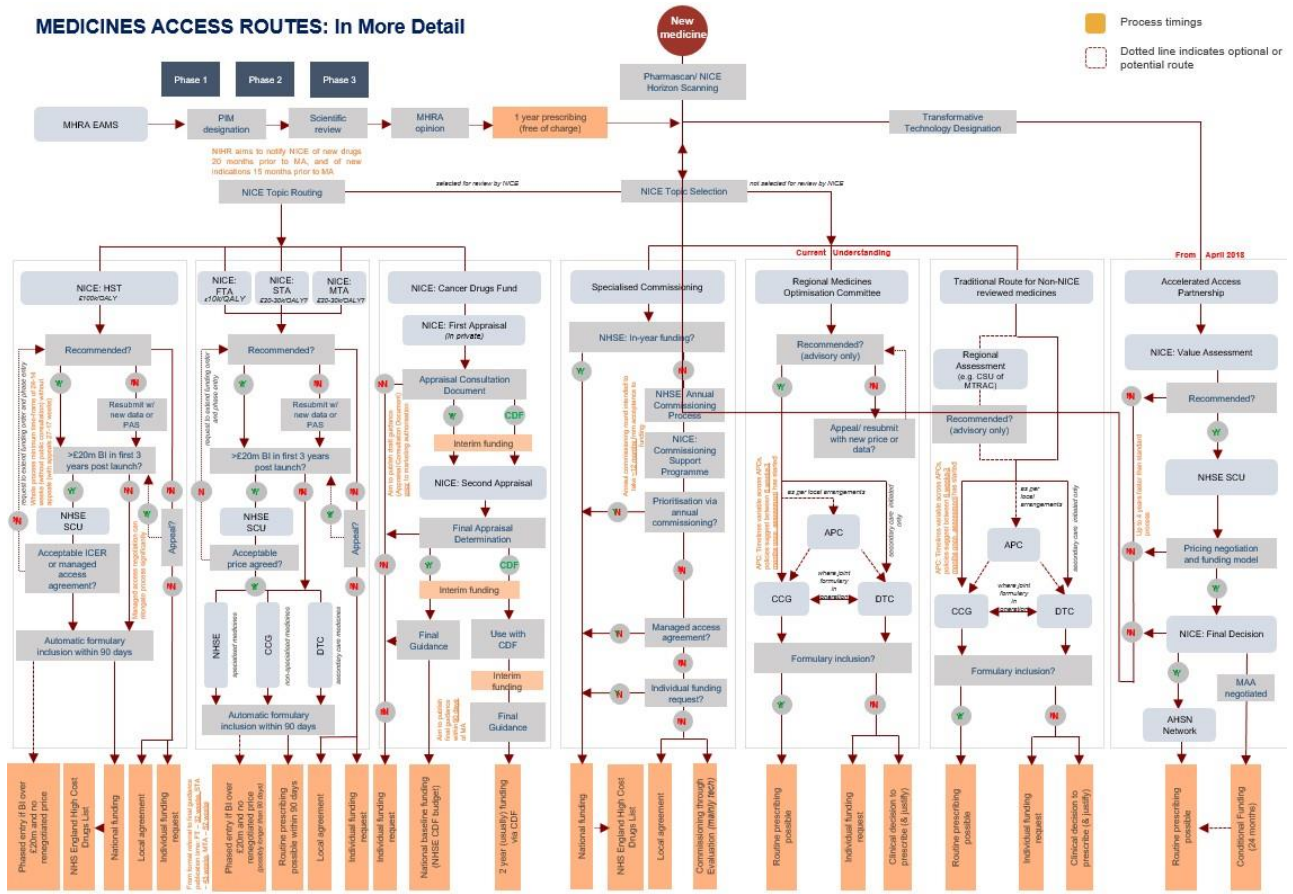
Source: IQVIA Market Prognosis, Sep 2018; IQVIA Institute, Dec 2018

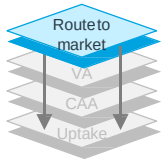
Medicines Access a complex maze, involving sequential discussions with multiple stakeholders

Current market access routes in England

Limited early engagement and planning discussions

Multiple, sequential discussions with different stakeholders





Several assessment processes using different approaches (NICE, NHSE, RMOCS, etc.)

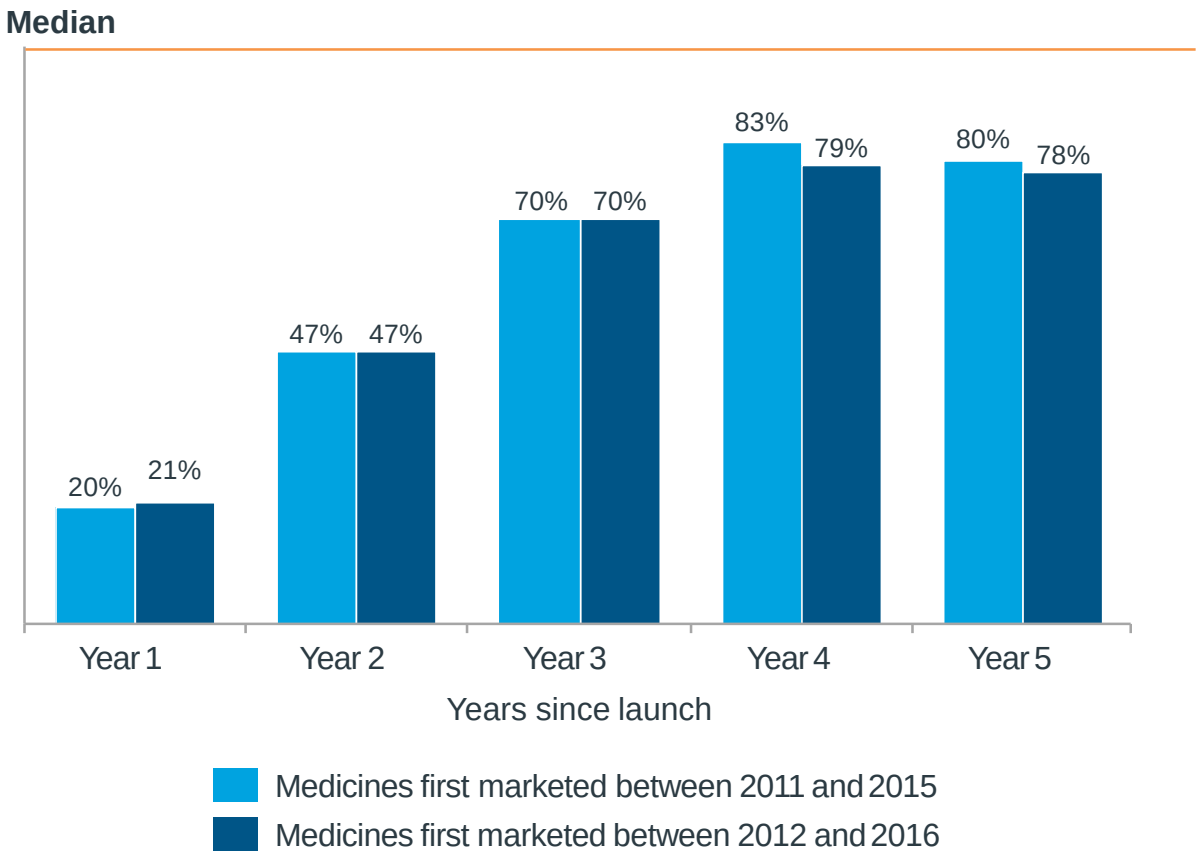
45% (233) of medicines[1,2] not referred to NICE between 2011-16; 12% routed to NHSE

1. Centrally approved medicines; 2. OHE. Reimbursement in the United Kingdom of medicines authorised between 2011 and 2016 via the European centralised procedure. October 2017.
Source: ABPI, OHE

Uptake of new medicines lags behind other countries at the detriment of UK patients

Per capita uptake of medicines in the UK relative to comparators'[1] median

Medicines w. a positive NICE recommendation



- Uptake in the UK remains relatively "low and slow" for NICE approved medicines
- Underpinning factors include
  - Further qualification of NICE guidance
  - Delays in making funding available
  - Delays in adjusting patient pathways
  - Bias towards clinical conservatism
- Uptake of medicines not reviewed by NICE seems to be deteriorating
  - Relative uptake in year 5 is 9 percentage points lower for medicines first marketed between 2012-16 versus 2011-15

Australia, Austria, Belgium, Canada, Finland, France, Germany, Ireland, Italy, Japan, Netherlands, Spain, Switzerland, Sweden, USA Source: OLS, from ABPI analysis of IQVIA data

Significant achievements on value and access will see more flexible commercial options for products with a maintenance of the NICE threshold

UK PharmaScan/NHS Horizon Scanning

New medicines and indications

Topic selection & routing *Company engagement and greater dialogue with NICE/NHSE*

NICE Guidance

STA | **FTA** | **HST**

Commercial Access Process

(if a commercial agreement is required) Single process for commercial discussions with NHSE, NICE and company

CDF Retained

Commercial arrangements + data collection (non-cancer medicines)

Tailored uptake support for the most clinically and cost-effective medicines. UQ ambition for 5 categories

- **Development of enhanced horizon scanning process**
- Improved early engagement and planning
- **NHSE account management approach**

- **All** new medicines and significant indications will have an appropriate NICE appraisal, unless there is clear rationale for not doing so
- Alignment of oncology & non-oncology appraisal timings
- Mandatory funding for all NICE approved medicines
- (Reduced need for reliance on NHSE spec comm process, RMOC evaluations or local assessments)
- Maintenance of the baseline CE threshold
- Changes in value assessment methods to be worked on through NICE TA and HST methods reviews in 2019/20

- Development of a clear process for integrated commercial discussions with NHSE and NICE

- Additional flexibility for confidential CAAs on the table, including some for dealing with indication based pricing-NHSE Commercial Directorate

- Option to align devolved nations commercial arrangements
- Some clarity on tendering intentions and process

- Commitments to improve uptake

In addition, NHSE, NICE and Government has a much clearer understanding of the challenges that the current market access environment presents which wehope to take further forward in the LSC PMAP

There is a willingness from Government and NHSE to improve uptake for the most clinically and cost-effective medicines

Uptake commitments

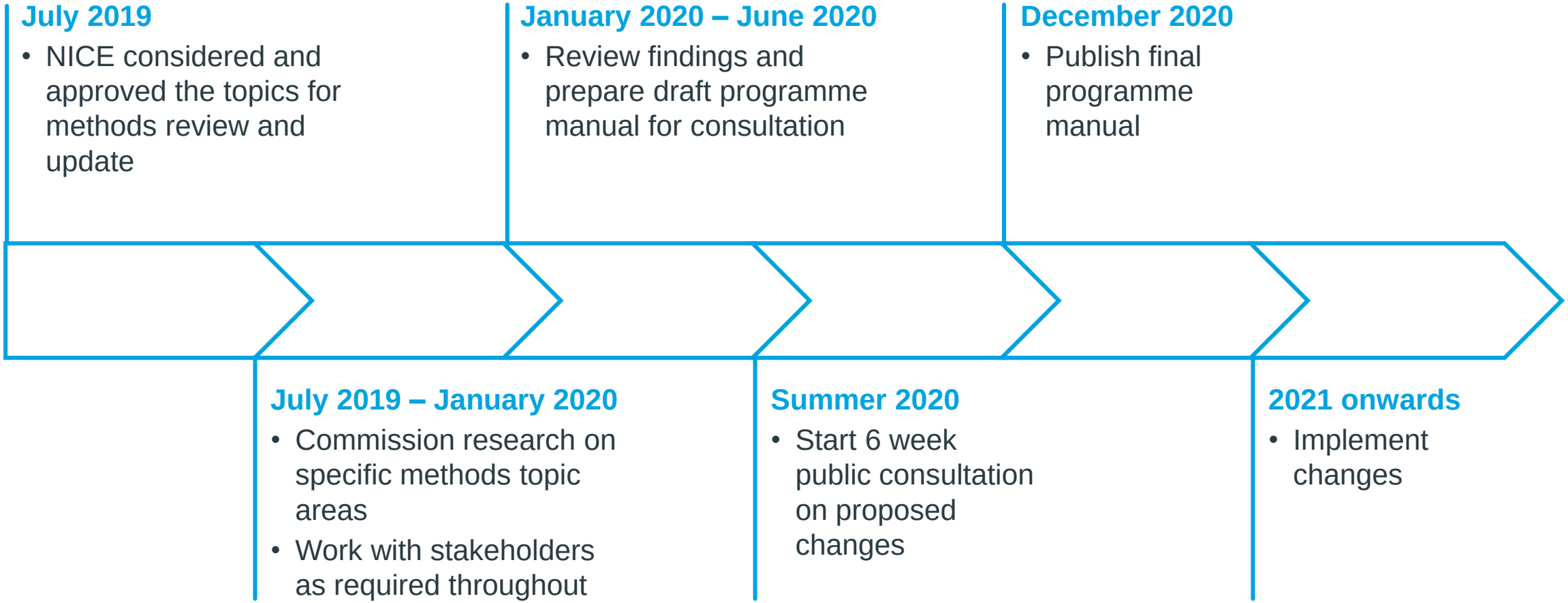
- All parties **aspire to see greater uptake** of current and future innovative, cost-effective medicines which provide significant health gain
- **Upper quartile target** for the five highest health gain categories during the first half of the scheme
- Continued **development of the Innovation Scorecard and other uptake measurement tools** to provide a more comprehensive approach to tracking uptake
- NHSE will **proactively provide tailored implementation support** to ensure uptake of cost-effective medicines which provide the most significant health gain
- Continued discussions on the **development of the data infrastructure** to enable improved information collection and generation of RWE, including on an indication-specific basis where appropriate

NICE plans to review its evaluation methodologies to ensure timely access to the wave of innovative products in development

- Purpose: to optimise NICE evaluation methods to support the ambition of the NHS to provide high quality care that offers good value to patients and to the NHS
- Why is this important?
  - More and more complex therapies are being developed
  - Pipeline of personalised therapies is growing i.e. CAR T therapies
  - Medicines are gaining EMA approval based on limited evidence

- Due to the increasing level of uncertainty, particularly in regards to complex therapies and treatments for rare diseases, it is becoming more and more difficult for NICE to determine the true value of products, resulting in delayed access for patients

NICE will open their proposal to consultation in 2020, with the plan to implement changes in 2021



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Consultation on the use of RWE in NICE appraisals

NICE are proposing to utilise broader sources of data and analytics to inform their decision making and guidance

NICE remit

Develop recommendations, advice and information through a diverse range of programmes to help the health and social care system to deliver the best outcomes for people using services with the resources available within the NHS

Purpose of this consultation

NICE wants to use broader sources of data and analytic methods to enhance their existing methods and processes and inform future guidance

Sources of data NICE are proposing to use

- A wide range of data sources are available for use and will depend on the review question
- Sources of data that NICE has already used or could consider using in the future include, but is not limited to:
  - Primary care and secondary care databases
  - Registries which collect data on how particular treatments are used
  - Surveys of people using health and social care services
  - Data collected on national trends (e.g. prevalence data)

NICE have identified a number of circumstances in which more extensive use of data could improve their methods and processes

When and why should these data types be used

- Situations where additional data or analysis could be used include, but is not limited to:
  - Where an evidence gap has been identified
  - To measure the effectiveness and cost-effectiveness of interventions in real-world settings
  - To demonstrate comparative effectiveness when the RCT comparator does not reflect real world practice
  - To monitor and evaluate intermediate outcomes of intervention
  - To establish the characteristics of the population of interest in practice
  - To improve tracking of guidance implementation, uptake and impact
  - To update guidance more efficiently than is currently done

NICE anticipates that these proposed changes will help improve their guidance, expedite updates on previously published guidance, and enhance understanding of the impact their guidance has on patients accessing health and social care services

The original remit of the AAC was to identify ‘breakthrough’ products to be fast-tracked into the NHS or improve uptake of already launched medicines with proven innovation

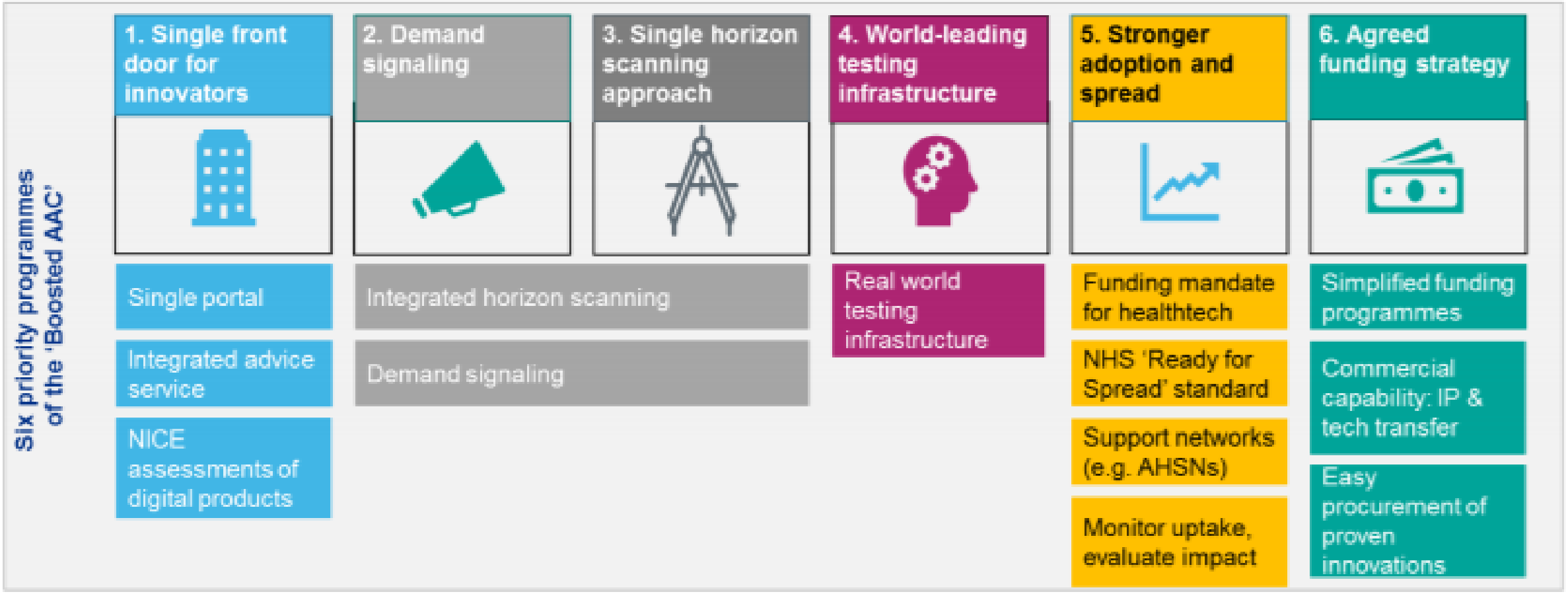
1. **5-10 products each year will receive ‘breakthrough’ designation which would enable:**
   - › Support allowing companies to accelerate clinical development
   - › Fast track through NHS’s approval process

2. **AAC also selected products that have an established and mature evidence base and are already on the market in the UK**
   - › The aim of this is to focus on already marketed transformative products where uptake and patient access is seen as challenging despite positive NICE or other relevant guidance being in place

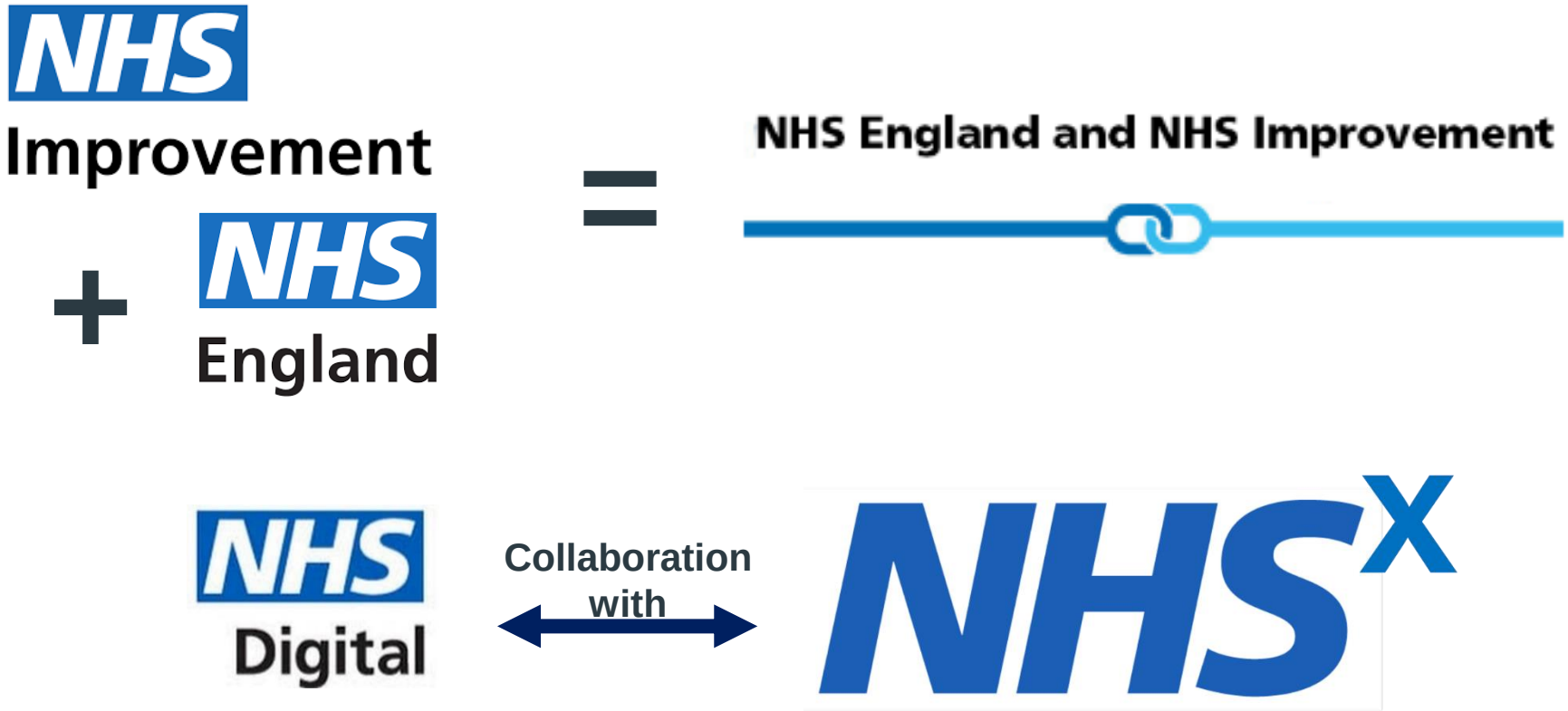
Products with proven innovation identified by the AAC

- HeartFlow Analysis for estimating fractional flow reserve from coronary CT angiography
- Placental growth factor (PIGF) based testing for suspected preeclampsia
- PCSK9 inhibitors: Repatha and Praluent
- High sensitivity troponin tests for early rule out of myocardial infarction
- Quantitative faecal immunochemical tests for colorectal cancer (3 tests)
- Cladribine for treating highly active relapsing-remitting multiple sclerosis in adults
- Urolift for lower urinary tract symptoms of benign prostatic hyperplasia

The remit of the AAC has expanded to include tackling some of the fundamental challenges in the innovation ecosystem



NHS Reorganisation (national)



Commercial Medicines Directorate

Roles

- Leading NHSE negotiations with the pharmaceutical industry
- SRO for the broader cross-organisational Medicines Value Program
- Build coherent commercial framework for drug reimbursement

Duties

- Drugs that trigger the £20m budget impact test (BIT)
- Cancer Drug Fund (CDF)
- NICE's Highly Specialised Technology appraisal programme (HST)
- NHS England's clinical policy process overseen by its Clinical Priorities Advisory Group (CPAG)
- A procurement function relating to medicines used in secondary care; Commercial Medicines Unit (CMU)

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Pillar 5: Uk will be ahead in 4th industrial revolution through its digital NHS agenda

The UK has data at scale, but needs standards, access approval process and data linkage to “de-silo” the insights

Strengths

- **Universal healthcare system** provides whole population perspective
- NHS number provides **unique patient ID**
- National coverage of **hospital inpatient administrative data** (Hospital Episode Statistics)
- Well-developed **ecosystem of registries** (e.g. cancer, stroke)
- Large scale **primary care electronic medical records** for research (e.g. THIN, CPRD)
- **Community prescribing** and dispensation data
- Emerging **unique data assets** (e.g. Genomics England)

Gaps

- Poor coverage of **hospital outpatient activity** in administrative data
- No routinely available national data about **hospital prescribing**
- Poor coverage of **outcomes data** (with the exception of mortality data), and early investment in **PROs** has not been sustained
- Prescribing and dispensation data **not routinely linked** to other data sources
- Primary care, secondary care and community care **data sources are often siloed**
- Some initial progress on interoperability, open standards and data access but **implementation has been slow**

The new digital strategy plan announced by Matt Hancock is investing more than £200 million in technology and AI

To transform the NHS into "the most advanced health system in the world"

Policy paper

The future of healthcare: our vision for digital, data and technology in health and care

Published 17 October 2018

Department of Health & Social Care

Key priorities

- New gold standard for acute, mental health, community and ambulance trusts in England
- An NHS app pilot scheme has been rolled out in Liverpool, Hastings, Bristol, Staffordshire and South Worcestershire
- NHS online services (book GP appointments, order repeat prescriptions, organ donation and end-of-life care etc)
- NHS organisations should be enabled to procure their own systems while maintaining inter-organisation communication.
- transparent and robust standards for IT systems in the NHS, ensuring they meet privacy and cyber security requirements.

The government has announced the NHSX as a new policy unit specifically to support the use of technology in the NHS

- Historically, NHS England led the IT strategy, national operational decisions, decided who gets money and what it should be spent on. DHSC has had oversight of higher-level digital policy. NHS Digital builds and provides some central IT systems, collects NHS data, and provides digital support services for providers
- NHSX will take over many of the digital responsibilities that currently sit with NHS England, including leadership of NHS digital strategy

- The move was needed because the NHS has been too slow on improving its IT systems, partly because responsibility was split across too many organisations
- The announcement comes as the Department of Health and Social Care publishes its “code of conduct” for how the NHS should partner with digital health companies, including how it extracts value from giving industry access to NHS patient data.
- “NHSX will have an open door to allow discussion with health tech industry that is developing products to make sure that we are harnessing the best innovation to improve the NHS”

- NHSX will be a joint-venture between NHS England/Improvement and the Department of Health and Social Care, with its own CEO. NHSE CIO Will Smart, CCIO Simon Eccles and interim Chief Digital Officer Tara Donnelly will move to NHSX. NHS Digital will now report to NHSX, rather than NHS England
- Responsibility for central funding for digital technology, handling central IT contracts, setting national policy for digital technology

Matthew Gould
The new CEO of NHSX

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Digital Innovation Hubs

Digital Innovation Hubs

- Funded through the Industrial Strategy Challenge Fund – £37.5 million investment in new Digital Innovation Hubs has been made across the UK
- The new hubs will help **connect regional health and care data with biomedical data in secure environments**
- The Digital Innovation Hubs will be led by Health Data Research UK (HDR UK), the national institute for data science in health, delivering on behalf of UK Research and Innovation
- The Digital Innovation Hubs programme were launched in Autumn 2018 with ‘demonstrator projects’ that est. approaches that will inform the design and delivery of the Digital Innovation Hubs
- Following this, in Spring 2019, HDR UK will invite regional partnerships of NHS, academia and industry to bid to establish a Digital Innovation Hub

Role and remit of Digital Innovation Hubs

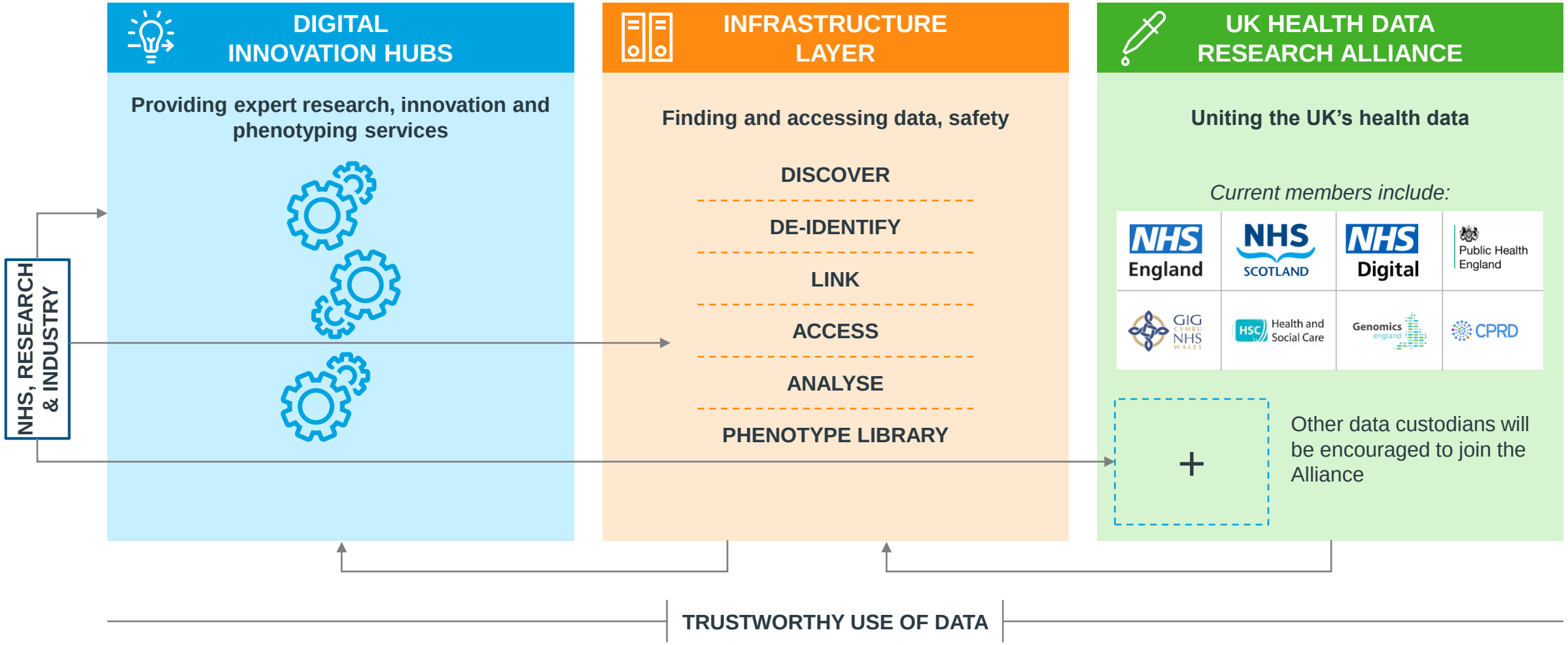
To provide a range of research data services, designed as advanced data handling and analytics environments, where academic, NHS and industry researchers will “breathe the same air” and be supported by people who understand the data, and a secure data processing area and flexible analytical workspace

Hubs will be able to act as a concierge service, using expert knowledge and skills to provide data curation, governance, analytics, computing power, physical location and safe havens for restricted data access within a trusted research environment

Hubs will provide expert services needed by academic, industry, healthcare professional and NHS users, and will build on areas of specialty. Hubs should leverage distinctive areas of expertise that meet a specific need, and have an identified market and users for the services

Three layers of the DIH Programme

Uniting the UK's health data to make discoveries that improve people's lives



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