

Health and Care Research Wales

Data for Research Programme

Health & Care Research
Wales
Support & Delivery Event
March 2023

Data for Research: UK Strategic Ambition

**UK Life Sciences
Vision**

***Saving & Improving Lives*
UK Clinical Research Vision**

Realise the UK's unique health data offer to become a world-leading destination for life sciences R&D

Increasing linkage and breadth of data, making it easy for approved researchers to securely access, analyse and use data via **Trusted Research Environments**

Supporting faster, effective, innovative and more diverse clinical trials enabled by data driven service
(Find, Recruit & Follow-Up)

Enables:

- A wider cohort of the UK population to be offered the opportunity to take part in clinical research
- Research data users will have a positive, streamlined experience

Data for Research Programme – Case for Change



Addressing large scale population health and policy evaluation questions

Advance scientific discoveries to improve treatment & save lives



Enable more people to participate in research relevant to them

Increasing the diversity of research participation



Increasing the speed and efficiency of clinical trials

Streamlining via process improvement rather than staff time



Increasing trial recruitment & improving time to target

Enabling innovative, pragmatic study designs

Data for Research: Wales starting point

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Major strength in Wales

But...

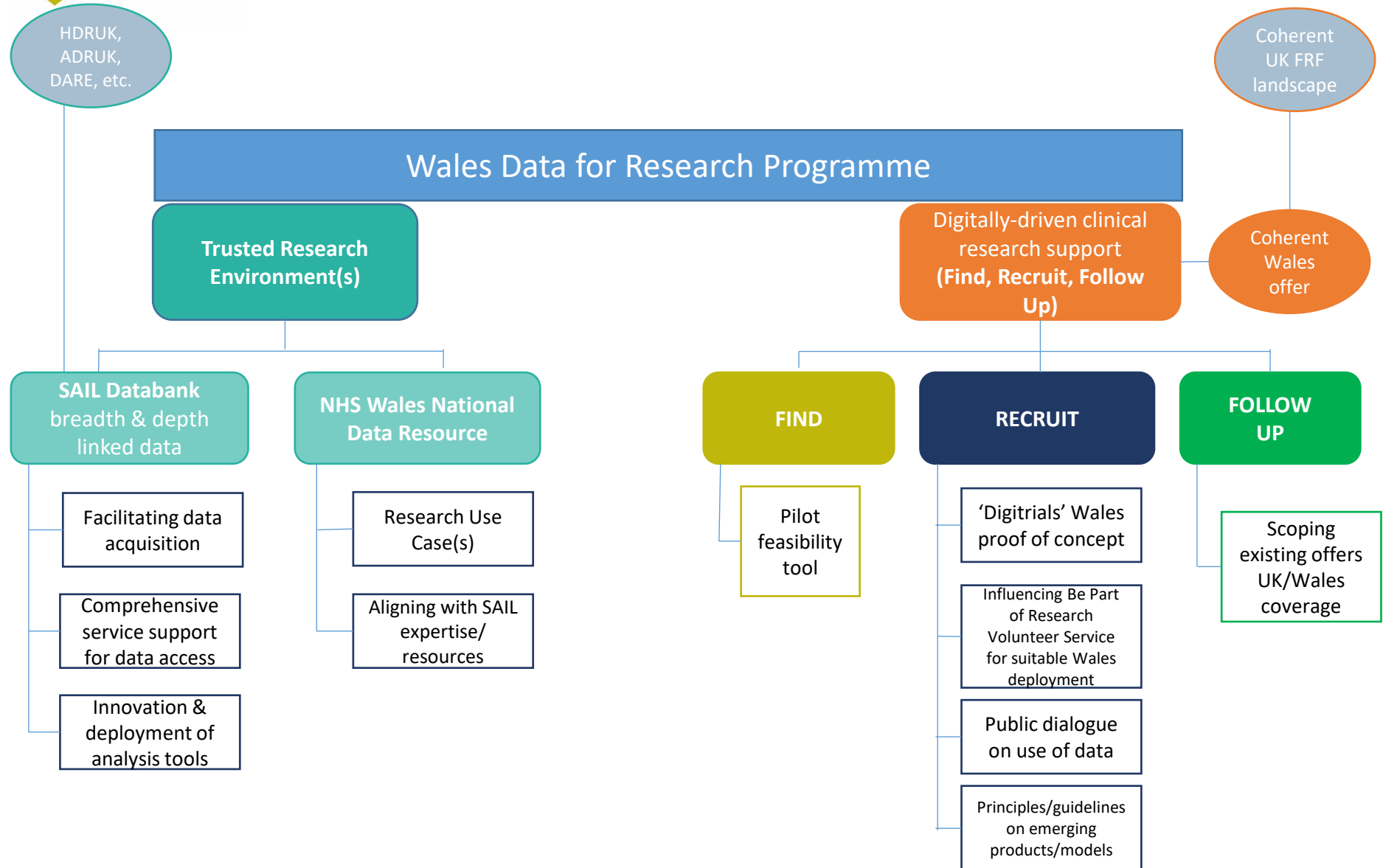
huge investment in England means others are catching up

Significant gap in Wales

But...

Other UK developments in their infancy too

Data for Research Programme



Trusted Research Environment(s)

SAIL Databank

- Budget and deliverables agreed as part of the 2020-25 Infrastructure
- Continuing to build on strengths and expertise
- focus on SAIL role within as Wales 'national research data infrastructure'

NHS Wales NDR

- Research use-case specified in the original business case, but awaiting details on specific plans
- Data for Research Programme objective in this area is to ensure NDR developments complement HCRW strategy and policy agenda

SAIL Databank – Responding to Covid

June 2020

# of COVID-19 Projects by TRE stage (change from previous report)	England (NHS Digital Data Processing Service)	Scotland (National Data Safe Haven)	Wales (SAIL Databank)	Northern Ireland (Honest Broker Service)	Total
In development	44 (-)	33 (+3)	70 (+10)	6 (+3)	153 (+16)
Submitted for IG approval	5 (-)	0 (-5)	0 (-)	0 (-)	5 (-5)
Approved but not yet active	0 (-)	2 (-2)	1 (-)	0 (-)	3 (-)
Active research taking place	20 (+10)	24 (+5)	60 (+3)	0 (-)	104 (+18)

December 2021

# of COVID-19 Projects by stage (change from previous report)	Office for National Statistics Secure Research Service	England (NHS Digital Data Processing Service)**	Scotland (National Data Safe Haven)	Wales (SAIL Databank)	Northern Ireland (Honest Broker Service)	Total
In development	7 (+1)	10 (-3)	0 (-19)	54 (-3)	3 (-)	74 (-24)
Submitted for Information Governance approval	0 (-1)	15 (-7)	1 (-5)	0 (-)	1 (+1)	17 (-12)
Approved but not yet active	1 (-)	7 (+6)	18 (+2)	4 (+1)	1 (-)	31 (+9)
Active research taking place	37 (+1)	62 (-8)	107 (-5)	107 (+1)	4 (-)	317 (-11)
Completed projects	6 (-)	0 (-)	7 (+2)	77 (+13)	0	90 (+15)
Active Number of Researchers	394 (-)	12 (-)	<i>Not available</i>	229 (-4)	10 (-)	645 (-4)
Average time from application to active research	128 days	<i>Not available</i>	13 days	7 days	78 days	

Source – HDR UK Reports to SAGE

Digitally-driven clinical research support (Find, Recruit, Follow Up)

FIND

Pilot Feasibility Tool

- Objective: to build and pilot a data-driven feasibility tool - drawing on SAIL data (anonymised data) to rapidly identify pools of potential participants (numbers only) against inclusion/exclusion criteria
- to support Health and Care Research Wales Delivery Staff complete expressions of interest and to target deployment of delivery resources
- Ability to build and run queries rapidly, giving fast estimates against sponsor queries
- Expecting MVP to be ready to begin using in next few weeks

Digitally-driven clinical research support (Find, Recruit, Follow Up)

RECRUIT

- Entire ecosystem of approaches and tools being developed, some bespoke for Wales and some with UK wide coverage.
- Multiple products available/ in development, will suit different study types. Interaction between services also important to give coherent UK approach
- Also, more future looking work on potential to change the regulatory environment for appropriate use of data, underpinned by public engagement to explore attitudes

Emerging UK 'RECRUIT' ecosystem



other
research
registers



Multiple
commercial
products



DigiTrials
Wales

Emerging UK 'RECRUIT' ecosystem



other
research
registers



FARSITE

Multiple
commercial
products

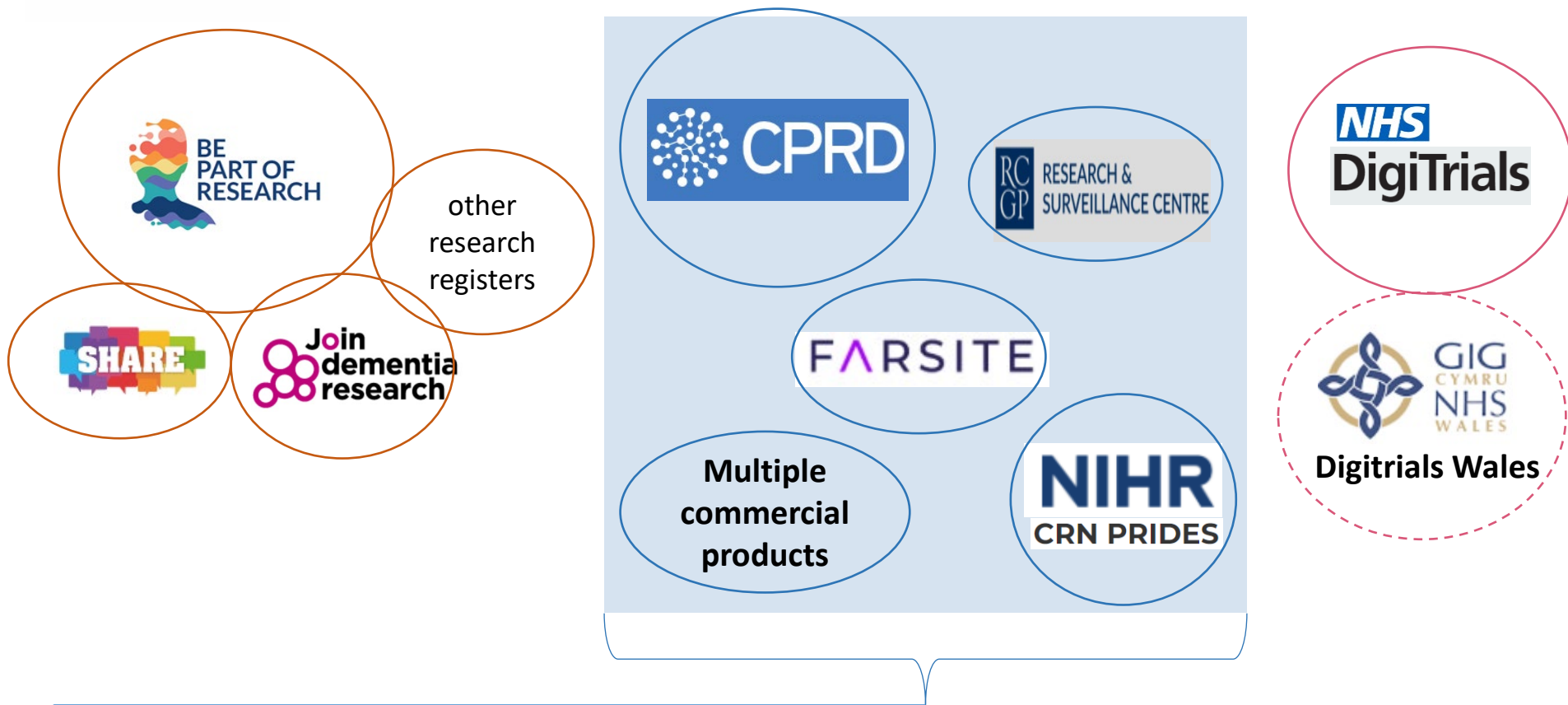
NIHR
CRN PRIDES



DigiTrials
Wales

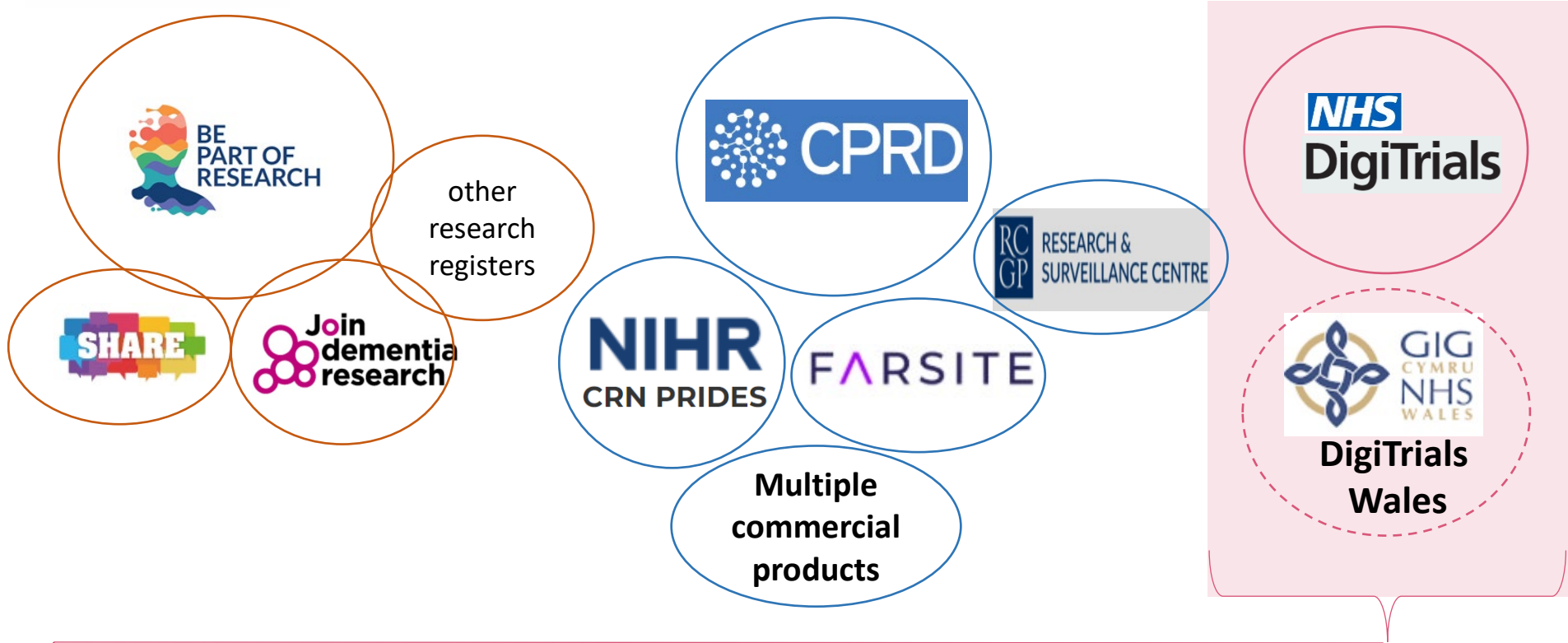
- Pro-active individuals opt-in 'consent to contact'
- Requires complementary promotion/engagement activity to drive sign up
- NHS England led project aims to create interoperability between registries
- UK wide Be Part of Research being positioned as the 'primary' register

Emerging UK 'RECRUIT' ecosystem



- Predominately primary care orientated tools, requiring sign-up by individual GP practices
- Collated, anonymised databases searched for inclusion/exclusion, and results pushed back to local GP for re-identification & approach
- Products in this space all effectively in competition with each other

Emerging UK 'RECRUIT' ecosystem



- Centralised search of patient records, and direct approach to individual (via letter)
- Based on narrow set of legal Directions & CAG approval (under COPI Regs) for each study using the Service
- Type of studies this service available to currently dictated by what HRA CAG will accept as appropriate to use this method

Digitally-driven clinical research support (Find, Recruit, Follow Up)

RECRUIT

'Digitrials' Wales proof of concept



- Build proof of concept service - a NHS Wales service to use patient identifiable data to identify and approach individuals eligible for specific trials, giving them opportunity to make decision on whether they wish to participate.
- Will require 2 Legal gateways – specific WG legal Direction to DHCW & study by study CAG Approval to enable this service to operate.
- DHCW have been commissioned to develop a proposal for the development and implementation of this service, collaborating with SAIL expertise.
- Project plan will include public involvement and stakeholder engagement elements

Digitally-driven clinical research support (Find, Recruit, Follow Up)

RECRUIT

Be Part of Research Volunteer Service



- NIHR CRN is building a 'Volunteer Service' website and tool to support connecting patients with research trials
- Concept is an opt-in 'consent for contact' register, individuals sign up and provide demographic/condition interest information.
- Portfolio studies will then be able to search the register to find individuals who may be eligible for their trial and communicate with them (via Be Part of Research team)
- A UK Wide Service. Arrangements underway for Welsh language standards compliance & arrangements for operational relationship with Health and Care Research Wales Delivery team
- Connections being made to NHS app in England. Wales considerations yet to be explored.

Study Search

- Public facing, searchable list of open research studies across the UK
- Keyword & location based search function
- Automatic feed, with weekly refresh, from ISCTN, CT.gov & CPMS

Volunteer Service

- Individuals able to register interest in being contacted about studies
- BPoR team manage 'match' of studies to individuals
- Private beta phase, with major public launch expected spring/summer

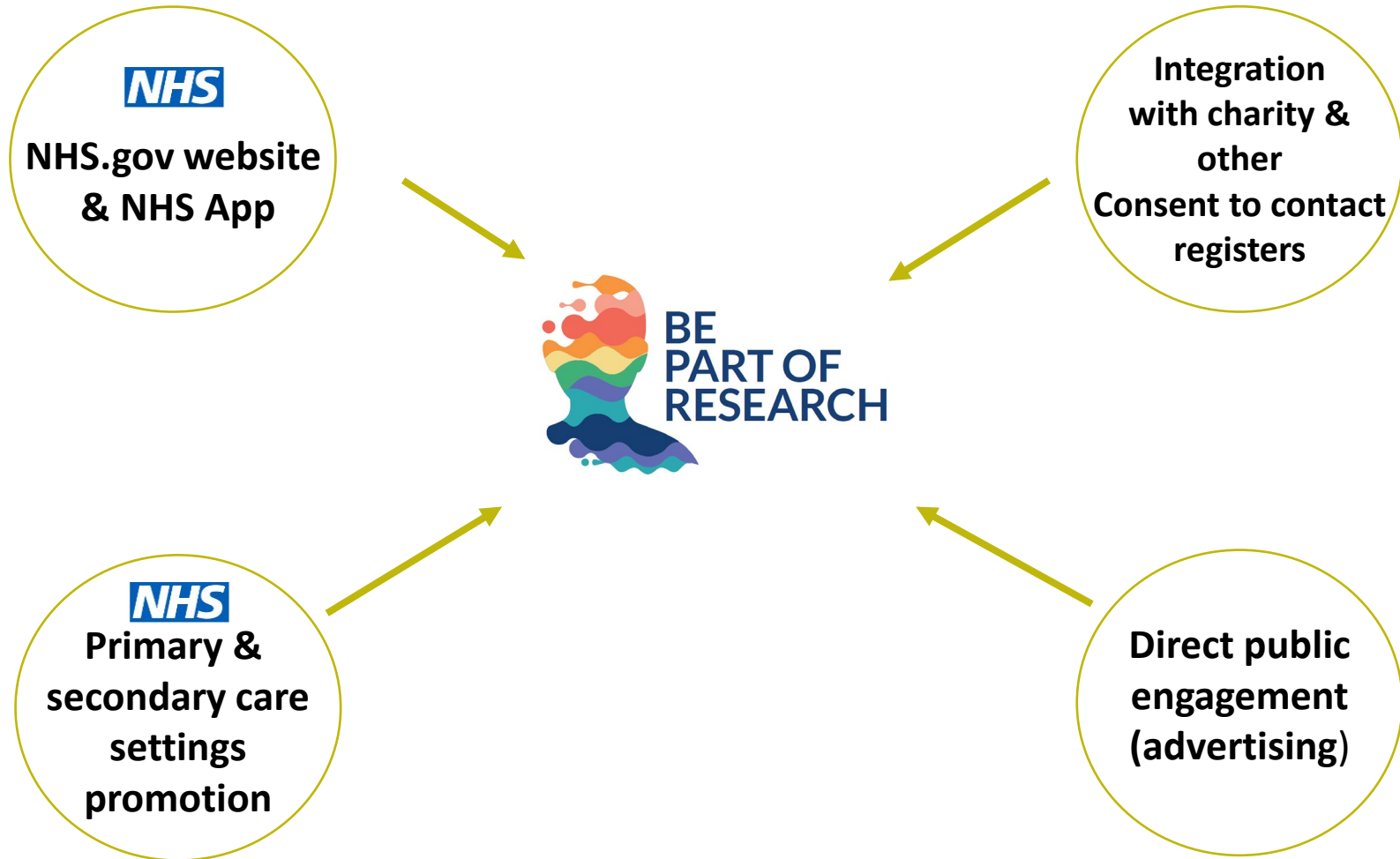
Vaccine Research Register

- Separate register of approx. 500k people
- Consent to be contacted about covid & non-covid study opportunities
- Coordinated by BPoR team

Volunteer Service

- Volunteers give consent for contact for the areas or research they are interested in and studies of national importance
- The Be Part of Research team contact the volunteers by email to signpost them to studies that match what they may be interested in
- The email will contain a link to the study's website, pre-screener or other contact mechanism agreed with the Be Part of Research team
- The volunteer then follows the study's agreed processes

Participant Routes to Register



Digitally-driven clinical research support (Find, Recruit, Follow Up)

RECRUIT

Deliberative Public Dialogue



- Appropriate use of data determined by current law & IG arrangements, shaped by public attitudes (or perception of them).
- 1st step - Commission piece of work to explore attitudes to how identifiable data could be used to identify and approach individuals in Wales for research based on Wales-specific criteria. Collaborating with the wider 'data promise' public dialogue discovery phase
- Aiming for deliberative engagement exercise(s) (e.g. citizen juries type approach).
- Wider stakeholder/PPI engagement planned to complement engagement exercise, via existing networks and groups
- UK wide discussion on potential changes to COPI legislation

Digitally-driven clinical research support (Find, Recruit, Follow Up)

RECRUIT

Principles/guidance on emerging products



- Increasing market of commercial and non-commercial organisations offering digital recruitment tools to sponsors and delivery organisations.
- Several products, particularly in primary care space, operate IG model that assumes acting on behalf of the care provider or identifiable data can only be seen by the care provider.
- There is nervousness in NHS IG community about how to deal with these models of practice
- Many models are arriving packaged as part of a funded study requesting delivery & set-up support, and IG staff are uncertain how to handle, preventing/delaying studies from being set up
- Objective is to work with HRA and NIHR CRN to provide some consistent advice/guidance to IG colleagues on what should be checked/assessed

Digitally-driven clinical research support (Find, Recruit, Follow Up)

FOLLOW UP

Scoping existing offers UK/Wales coverage

- Currently, it is a Researcher driven decision on how they wish to follow-up participants (once consented on trial), with multiple options available
- Initial scoping work to begin – opportunity for dedicated Wales service offer via SAIL (expanding on what is available already) or via DHCW & the National Data Resource

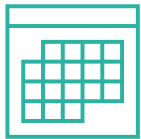
In Summary!



A broad, complex programme of work



Keen to develop solutions as rapidly as possible – there are already studies waiting to take advantage and opportunities to enhance our research delivery efficiency



Also need to manage expectations – there are limited resources; DHCW is building R&I infrastructure from small starting capacity; conversations with data controllers take time!



Public trust and acceptability is core to this entire programme and features both as specific activities and embedded within other necessary activities. Wider collaboration with other Wales and UK led activity is also essential