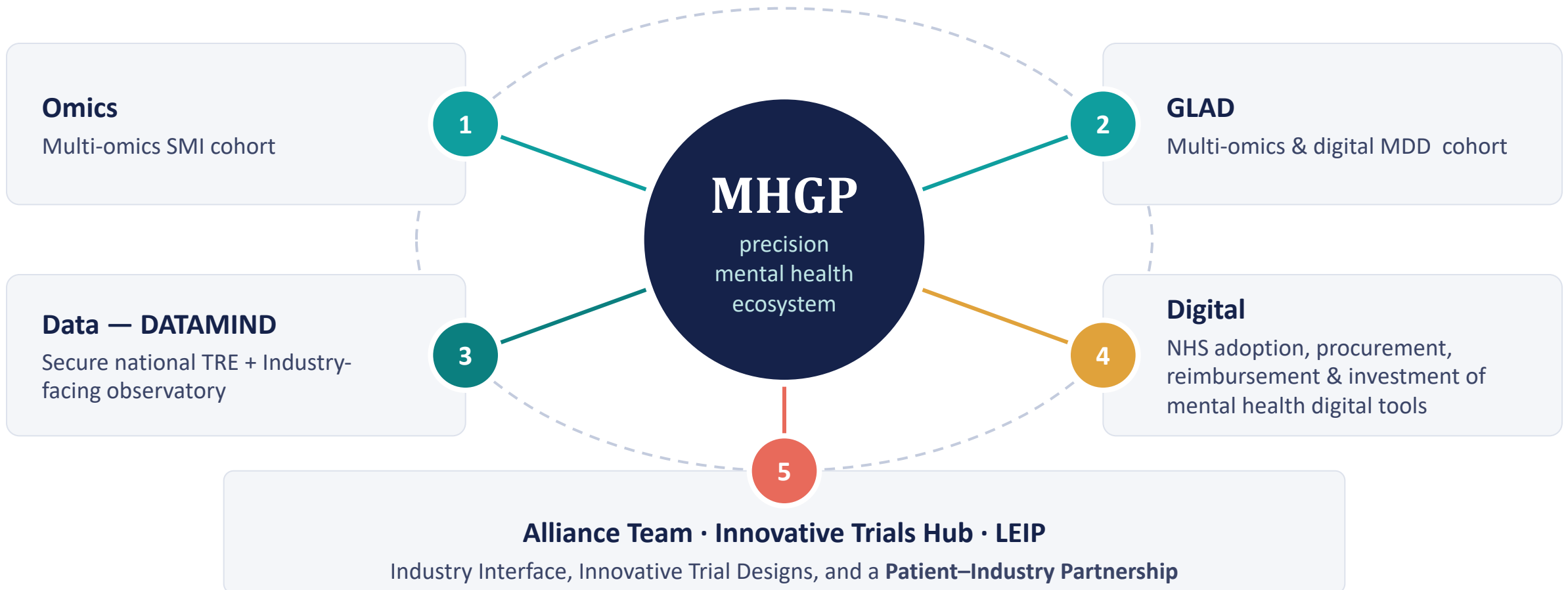


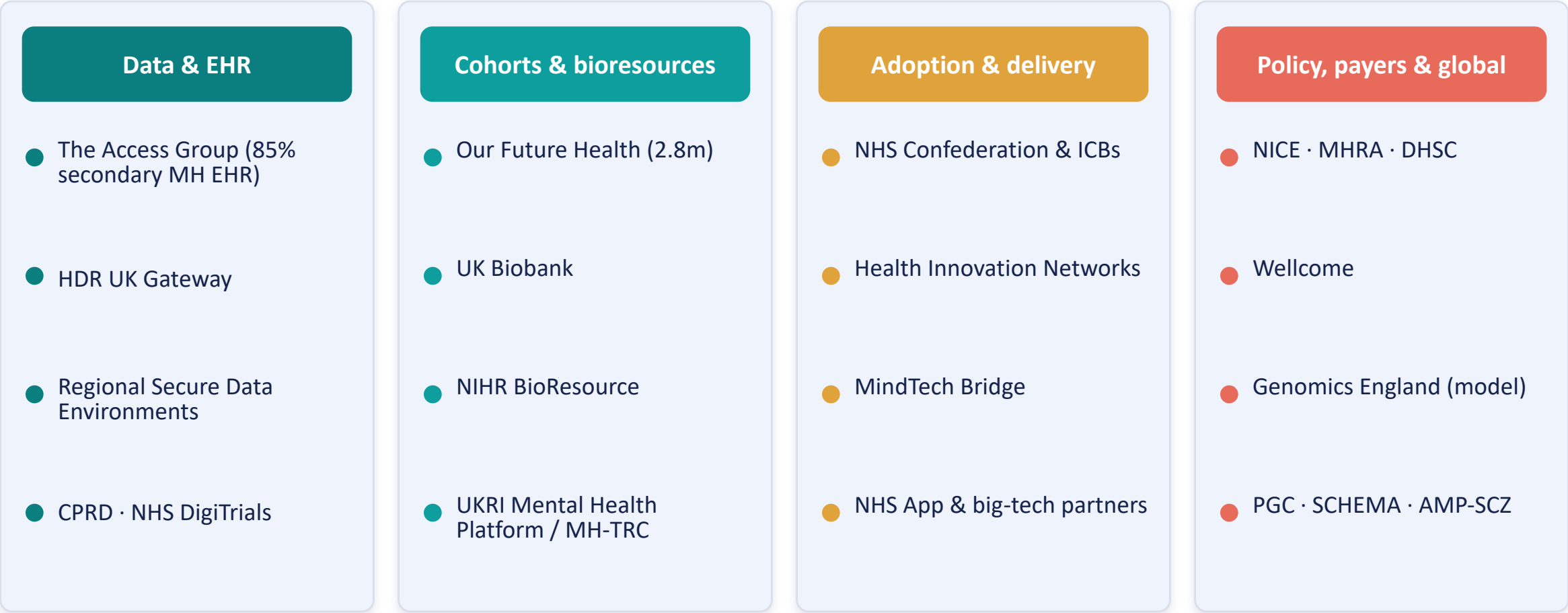
THE PROGRAMME

MHGP links national workstreams into one precision mental health ecosystem



Plugged into the UK — and global — ecosystem

MHGP assets are meant to connect with national infrastructure



Where mental-health trials fail — and how MHGP helps

Roughly 90% of CNS drug candidates fail in development, and mental-health trials are among the hardest of all. MHGP puts an asset at every stage where value leaks.



UK MHGP SWOT analysis

S Strengths

Internal · helpful

Which intrinsic strengths of UK MHGP are most relevant to you?

W Weaknesses

Internal · harmful

Which weaknesses should UK MHGP address as a priority?

O Opportunities

External · helpful

How can UK MHGP help you advance your mission and portfolio?

T Threats

External · harmful

What do you see changing that UK MHGP should prepare for?

BACK UP

APPENDIX

Glossary of abbreviations

Underlined terms link to the organisation or resource.

10YHP 10-Year Health Plan for England (2025)

AI / ML / LLM Artificial Intelligence / Machine Learning / Large Language Model

AMP-SCZ Accel. Medicines Partnership: Schizophrenia

AMT · ITH Alliance Management Team · Innovative Trials Hub

BioResource NIHR BioResource (recontactable)

Bridge2AI / BioFAIR NIH & ELIXIR-UK AI-ready data standards

CPRD Clinical Practice Research Datalink

DATAMIND HDR UK mental-health data hub / TRE

DHSC Department of Health & Social Care

DiGA Germany's fast-track for digital health apps

DPUK Dementias Platform UK

DTAC Digital Technology Assessment Criteria

EHR Electronic Health Record

EIS Early Intervention (in psychosis) Service

FAIR Findable, Accessible, Interoperable, Reusable

GLAD Genetic Links to Anxiety and Depression

HDR UK Health Data Research UK

ICB Integrated Care Board (NHS)

iPSC induced Pluripotent Stem Cell

LEIP Lived Experience Industry Partnership

LSSP Life Sciences Sector Plan (2025)

MAMS Multi-Arm Multi-Stage trial design

MAP Multiomics Analytic Platform (MHGP)

MDD Major Depressive Disorder

MH-TRC Mental Health Translational Research Collaboration

MHGP / MHG Mental Health Goals Programme

MHM Mental Health Mission (predecessor)

MHRA Medicines & Healthcare products Reg. Agency

NICE Nat. Inst. for Health & Care Excellence

NIHR Nat. Institute for Health & Care Research

OFH Our Future Health

OLS Office for Life Sciences

PBMC Peripheral Blood Mononuclear Cell

PGC Psychiatric Genomics Consortium

RCT Randomised Controlled Trial

RWE Real-World Evidence

SCHEMA Schizophrenia Exome Meta-Analysis

SDE Secure Data Environment

SeRP Secure eResearch Platform

SMI Severe Mental Illness

TRE Trusted Research Environment

TWiCs Trials Within Cohorts

UK Biobank UK biomedical research cohort

UKRI UK Research and Innovation

WGS Whole Genome Sequencing

WHERE 1 + 1 > 2

Cross-workstream synergies

The value compounds where the workstreams meet. Five connections that no single project could deliver:

Omics + GLAD

One transdiagnostic multi-omics resource — shared consent & sampling protocols mean psychosis and depression become a single comparative asset, not two silos.

Cohorts + DATAMIND + Access

Deep-phenotyped participants linked to of UK EHR, linked to Observatory recruitment simulator — a sampling frame for TWiCs and platform trials.

Digital + GLAD

Digital-phenotyping infrastructure funded in Digital powers GLAD's passive/wearable follow-up — digital biomarkers flow straight into the omics dataset.

LEIP + everything

Patient priorities shape omics outcomes (voice), the digital scorecard and ITH core outcome sets — aligning what is measured with what patients value, and de-risking the NICE case.

Alliance + ITH + Observatory

A company enters once and is routed to the right cohort, site, trial design and RWE service across all five workstreams — the UK's single industry front door.

How the data & cohort connections create value

Follow-on to the ecosystem map: what each connection enables, and why it matters.

Connection	What we can do together	Value proposition
<u>The Access Group</u>	Link MHG cohorts to ~85% of UK secondary mental-health EHR (RiO) inside the TRE	National-scale, longitudinal real-world outcomes; revenue returns to NHS Trusts
<u>HDR UK Gateway</u>	Publish MHG cohorts as discoverable, FAIR metadata	Global visibility — industry & academia find and request access fast
<u>Regional Secure Data Environments</u>	Federate mental-health data across regional SDEs	Wider, more representative catchment without moving sensitive data
<u>CPRD</u>	Blend primary-care records for context and comparators	External control arms, feasibility and safety-signal detection
<u>NHS DigiTrials</u>	Data-driven identification and invitation at population scale	Faster, cheaper, more representative recruitment (vs ~3% digital)
<u>Our Future Health</u>	Recall from a 2.8m-person cohort into MHG studies and trials	~30% response; deeply-phenotyped enrichment; a joint UK offer to industry
<u>UK Biobank</u>	Harmonise measures and benchmark against a global standard	Cross-cohort statistical power; positions UK data internationally
<u>NIHR BioResource</u>	Recontact and recall consented participants	A ready pipeline for experimental-medicine and precision studies
<u>UKRI Mental Health Platform / MH-TRC</u>	Shared protocols, hubs and Mood Disorder clinics	Interoperable data, no duplication, national delivery capacity

How adoption, policy & global links create value

Adoption and delivery partners, payers, regulators and global science — each a route to impact.

Connection	What we can do together	Value proposition
<u>NHS Confederation & ICBs</u>	Convene an innovation-ready Trust/ICB consortium	Multi-site adoption, pooled risk, a real testbed for national policy
<u>Health Innovation Networks</u>	Map readiness and implement regionally	Local delivery plus case studies of what works (and what fails)
<u>MindTech (MindTech Bridge)</u>	Accelerate commercialisation and scaling of digital tools	A route from evidence to NHS deployment and export
<u>NHS App & big-tech partners</u>	Partner on distribution and digital infrastructure	Scale, reach and interoperability for validated tools
<u>NICE</u>	Co-develop value/reimbursement models and scorecard alignment	A clear route to reimbursement — the missing incentive
<u>MHRA</u>	Industry-informed regulatory use cases for digital MH	Proportionate, faster, globally-influential regulation
<u>DHSC</u>	Embed MHG in national mental-health and data strategy	Policy durability and priority for the programme
<u>Wellcome</u>	Align mental-health strategy and fund regulatory work	Extra firepower and global agenda-setting
<u>Genomics England (model)</u>	Adopt a cost-recovery sustainability blueprint	A long-term, self-sustaining national resource
<u>PGC · SCHEMA · AMP-SCZ</u>	Contribute to and draw from global genomics consortia	World-leading discovery; the UK at the scientific frontier

Concrete value for industry & academia

For industry — pharma · biotech · digital

- Deep, curated, recontactable cohorts + biosamples across psychosis and depression
- Feasibility counts, phenotype definitions and recruitment simulation to de-risk trials
- Trial-ready NHS sites with embedded omics sampling capability
- Innovative trial designs (MAMS, adaptive, TWiCs, external control arms) and free methodology support
- A single front door: capabilities database, Founding Members, IP/gain-share models
- Clearer digital route: scorecard, procurement hub, reimbursement models

For academic researchers

- World-first 20,000-person multi-omics dataset linked to deep clinical, digital & EHR data
- AI-ready secure TRE with GPU compute, federated learning and open pipelines
- Cross-cohort scale via harmonised protocols with UK Biobank, MH Platform, PGC
- Recontact & recall for experimental-medicine and precision-psychiatry studies
- Training: omics summer school, data-science upskilling, industry placements
- A sustainable, FAIR, cost-recovery resource that endures beyond the grant

Biomarker-stratified trials in depression & psychosis



The problem for pharma

- MDD and psychosis are biologically heterogeneous, but trials still recruit on symptoms alone
- Unstratified populations dilute signal and inflate placebo response
- The result is high, expensive late-stage failure and delayed market entry



What MHGP delivers

- Multi-omic biomarkers (genomic, proteomic, metabolomic) on 20,000 deeply-phenotyped patients
- GLAD blood-based multi-omics + EHR to define responder subgroups
- Recontact/recall of consented participants for stratified enrolment
- ITH biomarker-guided and umbrella trial designs

VALUE

Higher probability of success, smaller and faster trials, and clearer go/no-go decisions — de-risking the single most expensive part of CNS development.

Workstreams:

Omics

GLAD

DATAMIND

Innovative Trials Hub

Feasibility, site selection & recruitment at scale



The problem for pharma

- Recruitment is the number-one cause of trial delay and failure
- Companies lack reliable incidence data to plan feasibility and choose sites
- Samples are often unrepresentative, weakening generalisability and access cases



What MHGP delivers

- Observatory recruitment simulator models incidence for the exact protocol
- Capabilities database of every UK site (biomarkers, imaging, catchment, readiness)
- Access EHR + NHS DigiTrials for data-driven identification and invitation
- Trial-ready NHS sites with embedded omics sampling across all four nations

VALUE

Accurate feasibility counts, optimised site selection and faster, more representative enrolment — turning the UK into the easiest place to fill a mental-health trial.

Workstreams:

Alliance / AMT

DATAMIND Observatory

Access

Omics sites

Platform, external-control & decentralised designs



The problem for pharma

- Classic two-arm RCTs are slow, costly and expose many patients to placebo
- Each asset bears the full fixed cost of its own trial infrastructure
- In-clinic-only assessment limits scale and real-world relevance



What MHGP delivers

- ITH Multi-Arm Multi-Stage platform trials — share control arms, add assets for a fee
- External / synthetic control arms from the TRE, CPRD and cohort data
- Trials Within Cohorts (TWiCs) using GLAD and the omics cohorts as sampling frames
- Decentralised delivery with digital-phenotyping and wearable outcome capture

VALUE

Lower cost per arm, reduced placebo burden, faster read-outs and multiple assets evaluated in parallel — economics that make mental-health R&D viable again.

Workstreams:

Innovative Trials Hub

DATAMIND

Digital

LEIP

Endpoints that matter and real-world value for payers



The problem for pharma

- Trial endpoints often miss what patients actually value, weakening the case for adoption
- Real-world and health-economic evidence is thin, so NICE/reimbursement is uncertain
- A regulatory approval with no reimbursement route delivers no return



What MHGP delivers

- LEIP priority-setting and voice/PROMs define outcomes that matter to patients
- Observatory generates real-world evidence and health-economic analyses
- Joint NICE/MHRA value pathway and the digital scorecard align evidence to criteria
- Live exemplar: the BMS Cobenfy real-world-evidence trial for a new NICE value model

VALUE

A de-risked, evidence-backed route from trial to reimbursement — the difference between a drug that is approved and one that is actually adopted and paid for.

Workstreams:

LEIP

DATAMIND

Digital

NICE / MHRA

AT A GLANCE

Eye chart — every key deliverable

Omics	GLAD (MDD)	Data — DATAMIND	Digital	Alliance · ITH · LEIP
20k multi-omics SMI cohort	12k new multi-omic MDD cohort	Secure national TRE (UK SeRP)	Digital MH scorecard (DTAC/NICE/MHRA)	Capabilities database (all UK sites)
Genomics/proteomics/metabolomics/epi genomics	32k digital longitudinal follow-up	EHR linkage via Access (85%)	National procurement hub	3-D cohort mapping + recruitment simulator
Risk & Recovery longitudinal sub-cohort	Voice + LLM outcome measures	AI-ready GPU + federated learning	Digital Navigators (& as-a-Service)	Founding Members + IP/gain-share
Multiomics Analytic Platform (MAP)	Relapse/response/suicidality pipelines	Observatory RWE service	≥8-Trust innovation-ready consortium	MAMS platform trial (≥3 industry arms)
Embedded NHS biosampling + SOPs	50k+ recontactable for industry	Industry Observatory front door	Blended investment + readiness tool	James Lind priority-setting (LEIP)
Trial-ready, recontactable cohort	Trial-ready by 2030	Cost-recovery sustainability	Technology Observatory	NICE/MHRA value & reimbursement work