



UNIVERSITY OF
BIRMINGHAM

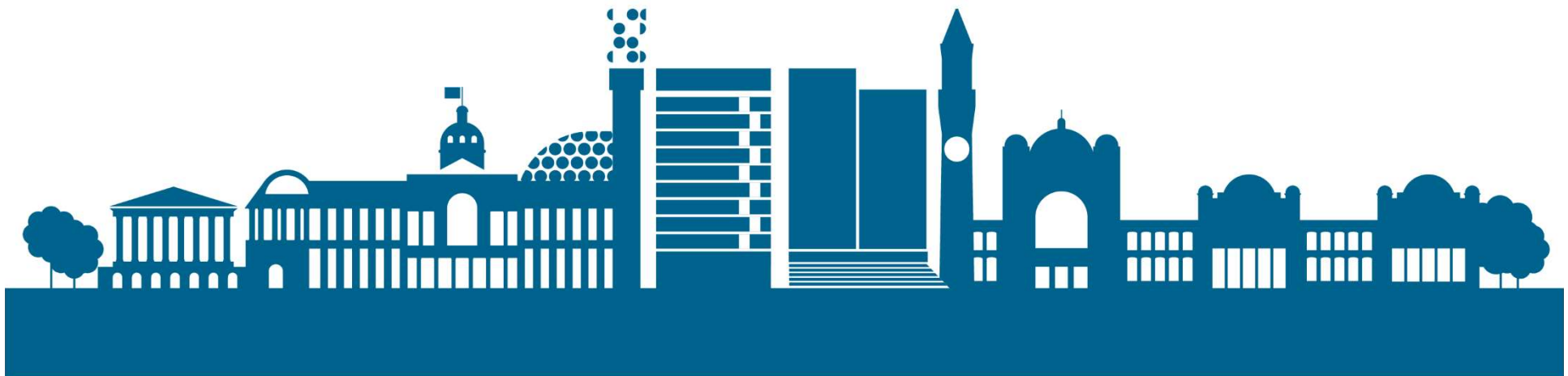


INSTITUTE OF
IMMUNOLOGY AND
IMMUNOTHERAPY

NAFLD BioResource

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NIHR BioResource

- >100k volunteers from the general population and included patients with rare diseases enrolled in the **NIHR BioResource**.
- Aim to recruit >500k volunteers in the next 5 years.
 - Provided information related to their health and lifestyle and biological samples, including DNA
 - Consented to be recalled for biomedical research studies according to their phenotype or genotype.
 - High density array (Affymetrix UK Biobank Axiom[®] Array) and metabolomic profiling (Metabolon) of DNA and plasma samples is in process to facilitate recall.



NIHR BioResource - Rare Diseases

- 12 Centres awarded in 2017 (+ Cambridge) to either BRCs or CRFs
- Created to support in depth phenotyping of patients with common and rare diseases



NIHR Common Disease BioResources

These BioResources will have individual coordinating team of their own, and will have separate ethics applications. These BioResources will be eligible for CRN Support.

Current Common Disease BioResources

- Inflammatory Bowel Disease
- Mental Health

Awarded

- Immune Mediated Inflammatory Disorders
- NAFLD
- Cerebrovascular Disease - pilot



Role of NIHR BioResources

- Providing an understanding of disease mechanisms and potential therapeutic targets.
- Application of 'omics in large cohorts offered by a national NIHR resource.
- Opportunities for translational research and new opportunities for economic growth through industrial collaborations.
- Recallable BioResources, with the potential to accelerate recruitment into clinical trials

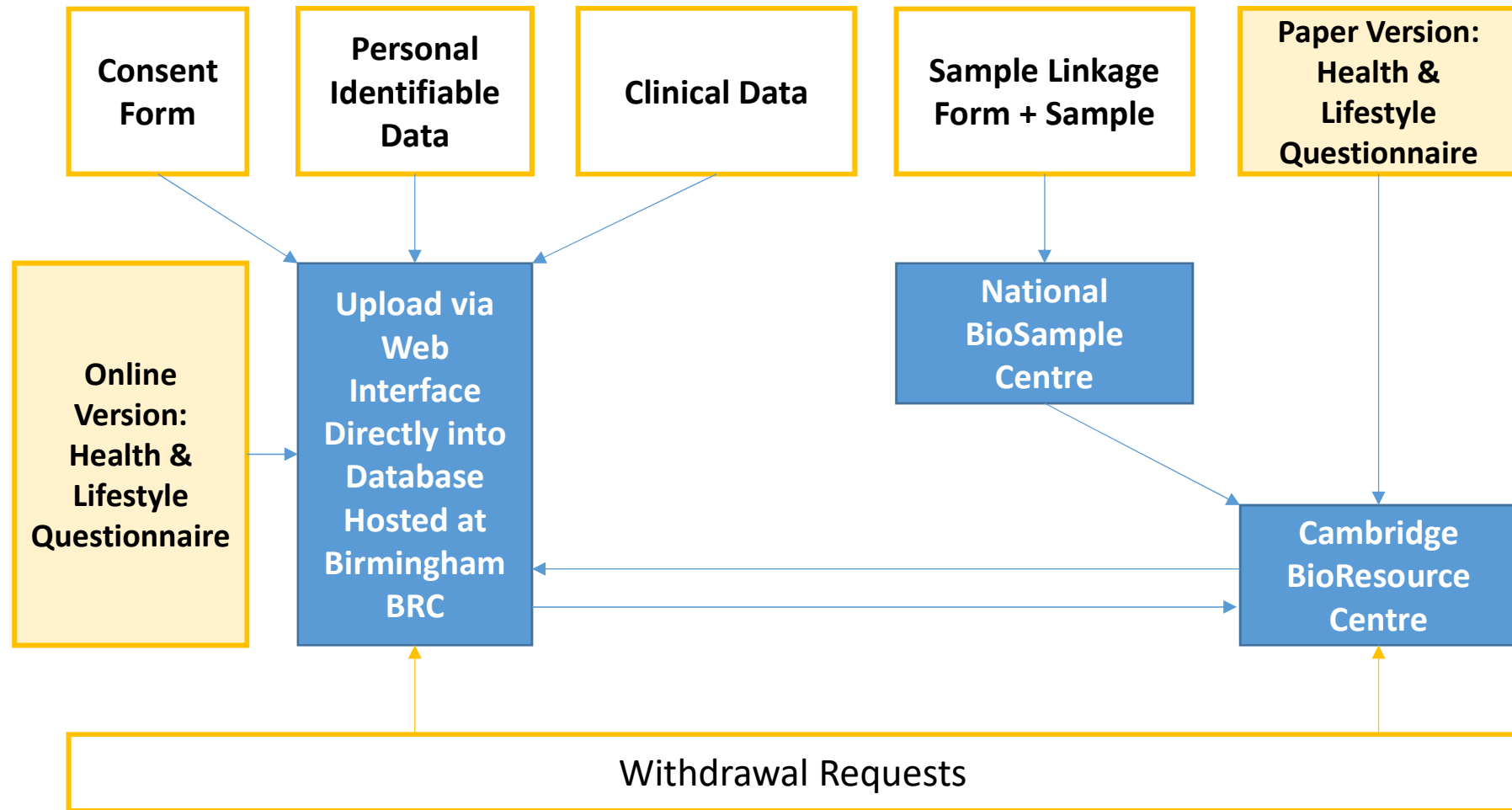


Goals of NAFLD BioResource

- Create and populate large scale UK registry
 - Initial target : 7,500 recruits across 80 sites
- Collect biological samples (including DNA)
- Collect information related to their health and lifestyle
- Obtain consent to enable recall for experimental medicine/industry studies



Data Pathway for Recruiting Sites



Health & Lifestyle Questionnaire

General Data (Collected in All BioResources)

- Demographics
- Comorbidities and family history
- General medication history
- Alcohol consumption
- Smoking

NAFLD Specific Data

- Diagnosis details
- Biopsy data
- Weight loss procedures
- Duke Activity Status Index (DASI)
- NAFLD medication history
- Coffee consumption

- Completed by patient either on paper form or electronically online
- Paper version is posted to Cambridge Team using Freepost envelope
- Electronic version entered directly into the NAFLD database



Clinical Data

Liver Histology

- Liver biopsy
- NAS score (if available)
- Steatosis grade
- Lobular inflammation
- Liver cell injury
- Evidence of NASH
- Fibrosis stage (Kleiner F1-F4)

Routine Bloods

- Urea & Electrolytes
- Liver Tests (ALP, AST, Bili...)
- Full blood count inc. INR and platelet counts
- Total cholesterol, HDL, Triglycerides
- AMA, ANA, SMA
- HBV, HCV, Haemochromatosis

Non-invasive Markers Of Liver Fibrosis

- Fibroscan date, median, IQR, CAP and Probe
- Serum ELF date and result

- Completed by research team directly into the NAFLD database
- Can be done retrospectively or during clinic



Value for Participants

- Access the BioResource data and samples
- Access the BioResource for recall of participants to 2nd Stage Studies
- Opportunity to accelerate identification of patients for clinical trials
- CRN Accruals, support and metrics



Progress to Date

- Contracting with funders signed off
- Programme Manager, IT Developer and IT Project Managers now in post
- PIS, Consent forms, and Questionnaires finalised, with PPI input
- Protocol drafted
- Database specification and design complete
- Ethics application in progress
- Steering group convened
 - first meeting 8th July 2019



Year 1 Key Milestones

- Ethics approval
– September 2019
- Recruitment at UHB (FPFV)
– October 2019
- Database Launch
– January 2020
- Recruitment at Nottingham & Newcastle
– January 2020
- Open 10 Sites
– March 2020
- Recruit 300 Patients
– March 2020



Timelines

	Year 1				Year 2				Year 3			
	Q1 Apr 19 - Jun 19	Q2 Jul 19 - Sep 19	Q3 Oct 19 - Dec 19	Q4 Jan 20 - Mar 20	Q1 Apr 20 - Jun 20	Q2 Jul 20 - Sep 20	Q3 Oct 20 - Dec 20	Q4 Jan 21 - Mar 21	Q1 Apr 21 - Jun 21	Q2 Jul 21 - Sep 21	Q3 Oct 21 - Dec 21	Q4 Jan 22 - Mar 22
Total Project Duration	[Yellow bar spanning all 12 quarters]											
Appoint Programme Manager (Bham)	[Green bar]											
Appoint 2 x Band 5s (Bham)		[Yellow bar]										
Appoint project Manager (Newcastle)		[Yellow bar]										
Appoint project Manager (Nottingham)		[Yellow bar]										
Develop and Launch Website		[Yellow bar]										
Develop database/Server set-up/Web platform	[Yellow bar]											
Convene NAFLD steering group/ ToR	[Green bar]											
Agree data sharing agreements with sites	[Yellow bar spanning all 12 quarters]											
Publicity/launch @ BSG	[Yellow bar]											
Publicity/launch @ BASL	[Yellow bar]											
Industry/ stakeholder meeting		[Yellow bar]										
Recruitment Start at UHB		[Yellow bar spanning all 11 quarters]										
Recruitment Start at Nottingham				[Yellow bar spanning 9 quarters]								
Recruitment Start at Newcastle				[Yellow bar spanning 9 quarters]								
Get 10 Sites Open by Y1 <small>Aim: 4 Bham, 3 Newcastle, 3 Nottingham</small>		[Yellow bar]										
300 Patients Recruited		[Yellow bar]										
Get 40 Sites Open by Y2 <small>Aim: 14 Bham, 13 Newcastle, 13 Nottingham</small>		[Yellow bar spanning 6 quarters]										
1500-2000 Patients Recruited		[Yellow bar spanning 6 quarters]										
Get 80 Sites Open by Y3 <small>Aim: 30 Bham, 25 Newcastle, 25 Nottingham</small>	[Yellow bar spanning all 12 quarters]											
5000-7500 Patients Recruited	[Yellow bar spanning all 12 quarters]											
Get 1-2 2nd Stage Studies Approved						[Yellow bar]						
Get 3-5 2nd Stage Studies Approved										[Yellow bar]		

