

# NHS

## SCOTLAND

NHS RESEARCH SCOTLAND



**DELIVERING RESEARCH EXCELLENCE**

# Hepatology Specialty Group -who we are and what we do

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# NRS Structure

- 7 Networks (SCRN, SMHRN, ScotCRN, SDCRN, SDRN, SPCRN,SSRN)
- 3 Champions with dedicated portfolio managers (RH&C, MSK and CV)
- 14 Specialties with Clinical Leads, nodal Portfolio Managers and administrative support (including Hepatology)
- Aim is for each study to be overseen by one Network or Specialty Group

## NRS: Hepatology Specialty Group

- Clinical Lead- Professor John Dillon
- Portfolio Manager- Sarah Kennedy
- Administrator- Jillian Strachan

## Role of the Hepatology Specialty Group

- Our role is to support the delivery of high quality clinical research (commercial and non-commercial) in Hepatology and manage participant recruitment to time and target, both for Hepatology studies which are led from Scotland, and studies led from other nations which Scottish sites are participating in.

# What studies do we support?

- High quality studies which are defined as research, involve NHS patients, data staff or facilities, and which are eligible for the Scottish research portfolio

# Eligible Funding

- Studies that are eligible for the portfolio in Scotland
- Automatically Eligible
  - Studies led by Scotland with a Funder appearing on the Scottish Eligible funders list
  - Studies led by England with a Funder appearing on the NIHR non-commercial partner list
  - Studies Sponsored by a commercial organisation

# Eligible Funders

- CSO
- NIHR
- MRC
- Alcohol Education and Research Council (AERC)
- British Infection Association (BIA)
- British Liver Trust
- Children's Liver Disease Foundation
- A full list is available on the NRS website



- Studies funded by an overseas government, overseas charity or Investigator Initiated (commercially funded but academically sponsored)
  - Meeting the following criteria:
    - Funding awarded in open competition
    - Peer reviewed
    - Clear value to the NHS
- Reviewed for adoption

# Benefits of Portfolio Eligibility

- Support from Networks and Specialty Groups
- Access to core infrastructure support- E.g CRF and Nurse resource
- Treatment and support costs involved in conducting research do not need to be covered by Grant.
- Board receives researcher support funding for eligible studies

# Research costing

Research costs- the costs of the R&D itself that end when the research ends

- Example- investigations, tests and assessments intended to answer the research question

Funding provided by the Grant

Treatment (or Excess Treatment) costs- the patient care costs, which would continue to be incurred if the patient care service in question continued to be provided after the R&D study had stopped.

- Example- supplying and administering the medication, patient follow up required as clinical management

These costs are covered by the Health Board. If costs exceed a set level per Health Board, a subvention to CSO can be applied for, to cover these costs

Service Support Costs-the additional patient care costs associated with the research, which would end once the R&D study in question had stopped, even if the patient care involved continued to be provided.

- Example-Obtaining informed consent, tests and assessments to ensure patient safety.

Funding for these activities are reimbursed to the Health Board retrospectively by CSO

# Researcher Support

- NRS Researcher Support is intended to support the activities of research active NHS employees in carrying out eligibly funded research or research adopted to the Scottish Portfolio
- Reimbursed to Boards retrospectively based on activity
  - Project based element
  - Recruitment premium
- Funding used to provide resource to support further research activity e.g. Research nurse

# How is our activity measured

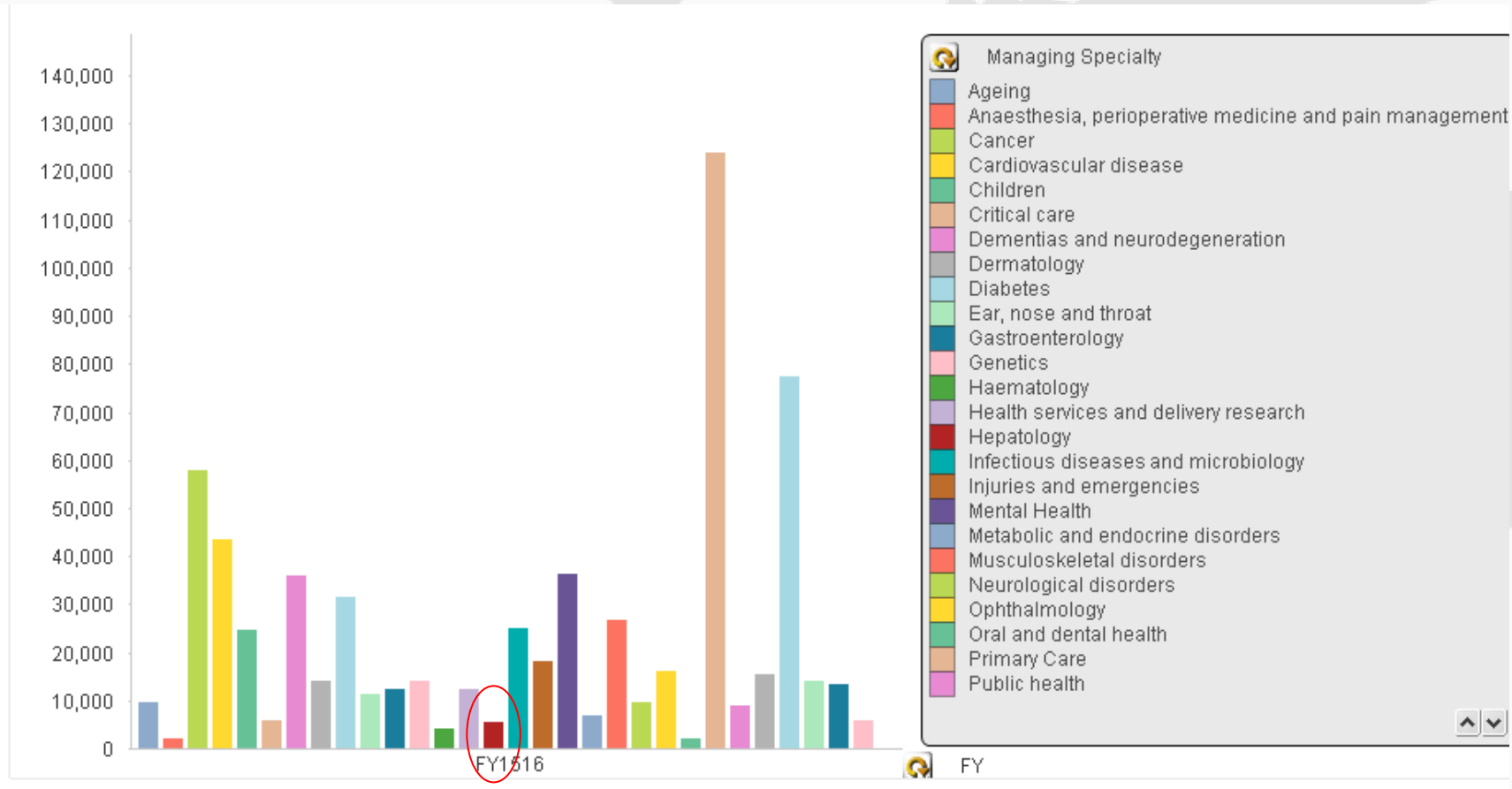
- Primarily based on recruitment and number of studies actively recruiting within each financial year (Apr-Mar)
- Less emphasis on complexity of studies
- We are only credited with recruitment to studies where we are the main Specialty
- Excludes studies which do not recruit, or where we act as Participant Identification Centres (PICs)

## Specialty Group Objectives

- The Strategy Board have set targets for financial year 2016/2017:
- for recruitment in each SG and Topic Network to be at least 10% of the corresponding English specialty
- for the number of studies showing recruitment on ODP to be at least 30% of the corresponding English specialty.

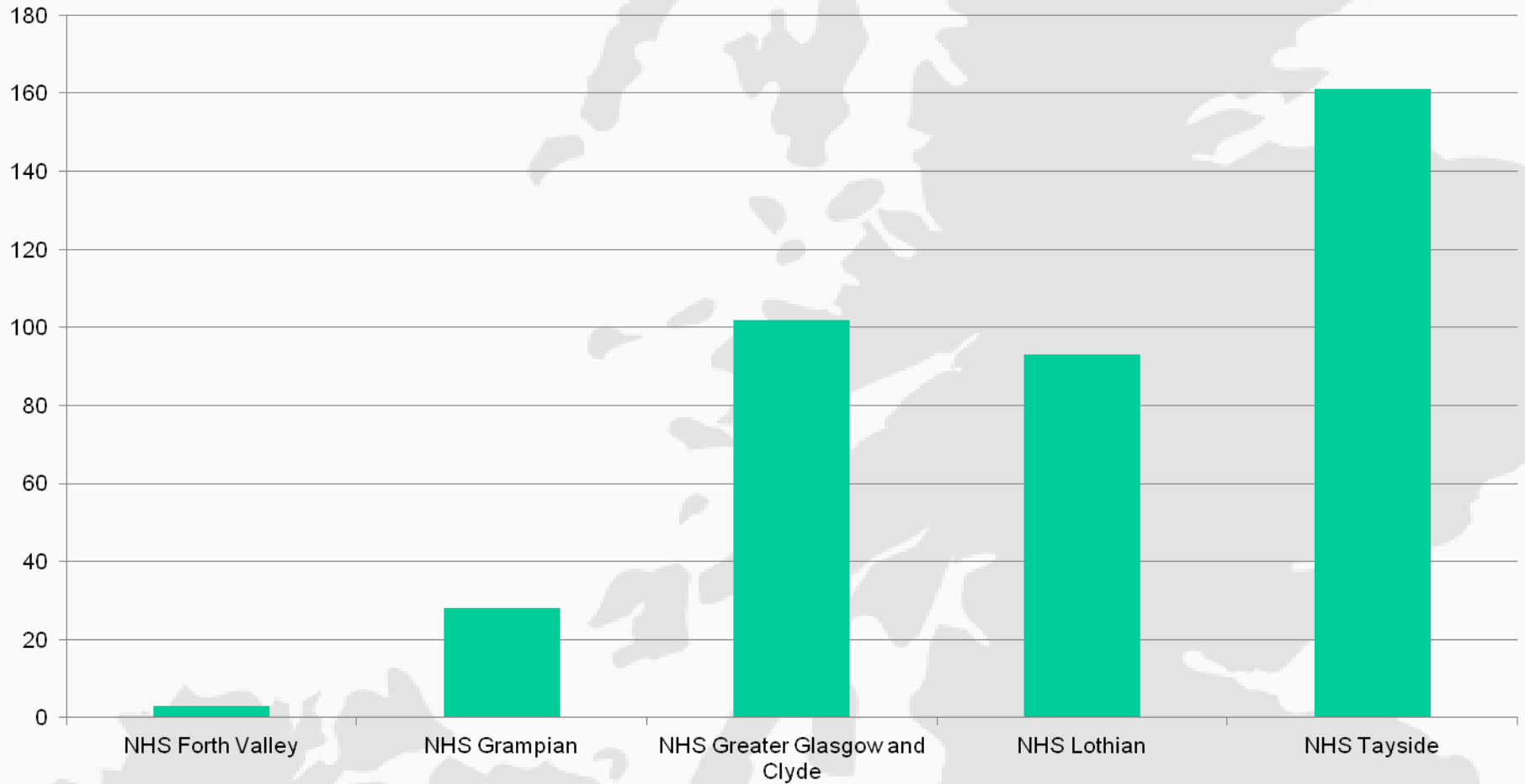


# National Picture

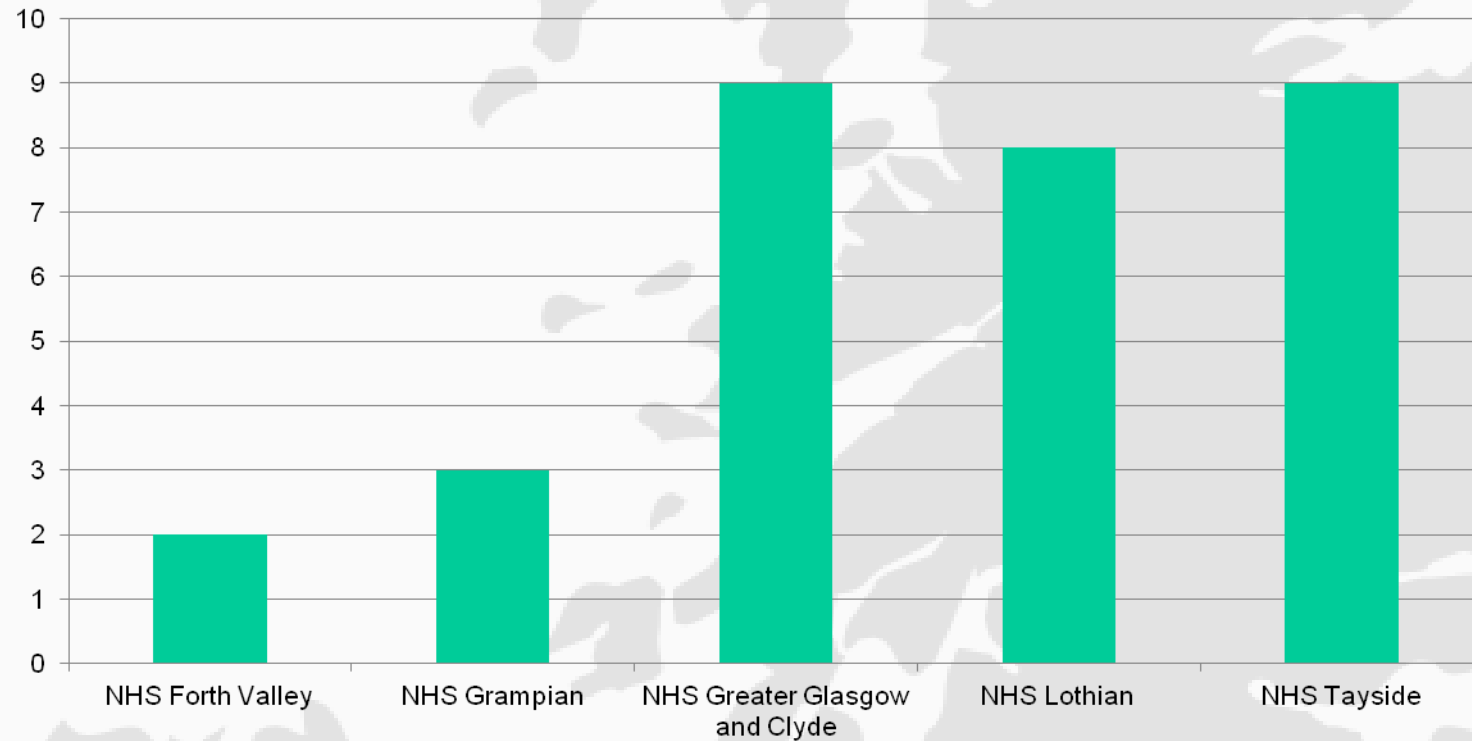


2015/16 Data Cut	England	Scotland	%
Number of studies	82	18	22%
Number of participants	5110	387	8%

## 2015/16 Hepatology Recruitment



## 2015/16 Hepatology Number of Studies



# Status of Active Hepatology Studies

data extracted from ODP 08/08/16

<b>58</b>	<b>Studies Open/Recruiting in the UK</b>
<b>49</b>	<b>Have recruited in England</b>
<b>5</b>	<b>Have recruited in Wales</b>
<b>11</b>	<b>Have recruited in Scotland</b>
<b>3</b>	<b>Have recruited in Northern Ireland</b>

# Active Hepatology Studies in Scotland

Study ID	Short Name	Opening Date	Closure Date	Participants
11582	HCV Research UK	01/02/2012	31/12/2016	2282
5630	PBC Genetics Study	06/12/2007	30/06/2017	369
6388	UK-PSC	01/08/2008	31/03/2017	162
13297	Eradicate HCV.	03/12/2012	31/08/2017	104
11862	Acute Hepatitis C UK study	17/02/2012	17/02/2022	50
17417	STOP-HCV Cirrhosis Study	05/01/2015	30/09/2018	48
18450	Albumin To prevenT Infection in chronic liveR failurE (ATTIRE)	21/05/2015	21/11/2017	13
17556	The UK-AIH Cohort	13/03/2014	31/03/2017	11
19458	HEPA 4545	09/09/2015	30/10/2016	11
19194	Liver Immunosuppression Free Trial ("LIFT"), version 1	08/10/2015	01/10/2017	4
18759	HEPA 3962 (HCV)	08/04/2015	22/11/2016	1

## Hepatology Studies

- Acute and chronic liver disease including liver failure
- The impact of identifying, screening and treating viral hepatitis
- Liver fibrosis and cirrhosis
- Normal and abnormal liver metabolism
- Genetic studies including pharmacogenetics
- Biomarkers
- Hepatotoxicity
- Treatment of portal hypertension

# Commercial Studies

- Not all commercial studies are on CMPS
- Studies difficult to identify on sReDA because there is no UKCRC health category for Hepatology, so studies are grouped in Infection
- Agreement required between Clinical Leads for Infectious Diseases and Hepatology to assign responsibilities for monitoring



# How can we help?

- Provide advice on study design and feasibility
- Peer review- for studies wishing to be considered for adoption
- Signposting funding opportunities
- Troubleshooting issues with poor recruitment
- Facilitating access to resource to support studies
- Sharing information on new studies

## Conclusions

- Unique system of support for clinical research within NHS
- Potential for increasing the number of Hepatology Studies throughout Scotland
- Scotland has the skills and infrastructure to support this
- Close scrutiny to ensure recruitment to time and target



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