Research & Development
Taighde & Forbairt

# Research Activity in the HSE and its Funded Organisations

## A report of staff engaged in research, research studies undertaken, publication output and research networks

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Seirbhís Sláinte Níos Fearr á Forbairt | Building a Better Health Service

January 2019

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# Glossary

| | |
|---|---|
| CNOH: | Cappagh National Orthopaedic Hospital |
| CT-IMP: | Clinical Trial of Investigational Medicinal Product |
| CHO: | Community Health Organisation |
| CFAA: | Medical consultant with a formal academic appointment |
| CUH: | Cork University Hospital |
| CHITIN: | Cross-border Healthcare Intervention Trials in Ireland Network |
| CÚRAM: | Centre for Research in Medical Devices |
| EEA: | European Economic Area |
| EU: | European Union |
| EudraCT: | EU Clinical Trials Register |
| GUH: | Galway University Hospital |
| HCP: | Healthcare Professional |
| HEI: | Higher Education Institution |
| HG: | Hospital Group |
| HPRA: | Health Products Regulatory Authority |
| HR: | Human Resources |
| HRCS: | Health Research Classification System |
| HSCP: | Health and Social Care Professional |
| HSE: | Health Service Executive |
| ICGP: | Irish College of General Practitioners |
| ICH GCP: | International Conference on Harmonisation, Good Clinical Practice |
| IDSI: | Infectious Diseases Society of Ireland |
| ISGE: | Irish Society of Gastroenterology |
| LUH: | Letterkenny University Hospital |
| MUH: | Mayo University Hospital |
| MUH, Cork: | Mercy University Hospital, Cork |
| NMH: | National Maternity Hospital |
| NRH: | National Rehabilitation Hospital |
| NSAI: | National Standards Authority of Ireland |
| NUI Galway: | National University of Ireland, Galway |
| OLCHC: | Our Lady's Children's Hospital, Crumlin |
| PI: | Principal Investigator |

| | |
|---|---|
| QUB: | Queen's University, Belfast |
| R&D: | Research and Development |
| REC: | Research Ethics Committee |
| RCSI: | Royal College of Surgeons in Ireland |
| RVEEH: | Royal Victoria Eye and Ear Hospital |
| SJH: | St James's Hospital |
| SVUH: | St Vincent's University Hospital |
| SFI: | Science Foundation Ireland |
| SUH: | Sligo University Hospital |
| TCD: | Trinity College Dublin |
| TUH: | Tallaght University Hospital |
| UCC: | University College Cork |
| UCD: | University College Dublin |
| UHL: | University Hospital Limerick |
| UL: | University of Limerick |
| ULH: | University of Limerick Hospitals |

# Acknowledgements

Sincere thanks to all the internal and external stakeholders who contributed with data and information, without which the compilation of this report would not have been possible: the Research Offices from the third level education institutions in Ireland, the Health Research Board, the Research Ethics Committees in the HSE and associated organisations, the Health Products Regulatory Authority, and all the staff members who answered the Research Survey 2018.

In particular we would like to acknowledge the support of Dr Virginia Minogue and our colleagues from the HSE Health Intelligence Unit and the National Library and Knowledge Service, Niamh Brennan from the Trinity College Dublin Library, Fionnuala Keane from HRB Clinical Research Coordination Ireland, and colleagues from the Health Products Regulatory Authority.

# Executive Summary

This study was carried out in response to the Action Plan for Health Research 2009-2013, which placed on the HSE the responsibility for establishing a benchmark of research activity in the health service against which opportunities can be identified, efforts coordinated and future research activity monitored.

This report presents the results of such a study as the first attempt to benchmark the research activity within the public health and social care services in Ireland. A variety of different accessible datasets were used as an indication of research activity and output. The results are described around four main categories: staff involved in research, research studies undertaken, publication outputs and Clinical Research Networks. These indicators show that the volume of on-going research is significant and that broad experience and capability across a variety of domains currently exists.

## Activity Indicator 1 — Staff Involved in Research

Information related to staff involved in research was explored using two approaches:

### 1) A national survey of self-declared research active staff

The national research survey received 1,904 valid responses from staff members who self-identified as being research active. It indicated that:

- Staff were engaged in research in all areas of the service, including acute and community settings, as well as national services and HSE corporate, and many were also linked to academia.
- The majority of respondents were based in hospitals (40%) and community-based healthcare organisations (31%).
- The Dublin Midlands Hospital Group (HG) was the one with the largest percentage of respondents followed by the South / South West HG. However, the largest proportional response rate[1] was from the National Children's HG, followed by the Dublin Midlands HG.
- Staff from the Health and Social Care Professions (HSCPs) represented 32% of the respondents, followed by Nursing and Midwifery (21%) and Medical Doctors (15%). Proportionally, the response rate[2] from Medical Doctors was highest.
- The majority of HSCP respondents were community-based, while the majority of Nursing and Midwifery and Medical Doctor respondents were based in acute hospitals.
  - The majority of community-based respondents were based in Community Healthcare Organisation (CHO) 7 covering Dublin West, Dublin South City, Dublin South West, Kildare, and West Wicklow.

1 Number of responses divided by total number of staff in that hospital group.

2 Number of respondents divided by total number of professionals in that category.

  - 48% of all Nursing and Midwifery respondents had a master's degree. Medical Doctors and HSCP respondents had the highest proportion of PhDs (23% and 22% respectively).
  - The majority of respondents engaged in independent research (able to carry out research without supervision) belonged to the Medical Doctor category.
  - Nursing and Midwifery respondents indicated that they were more prominently involved in enabling and assisting in research activity, and as early stage researchers.
- 60% of respondents had no association with the third level sector. The remainder 40%, indicated an association with the third level sector, either contractually bound or not.
- The majority of respondents spend between 1 and 10 hours conducting research per week.
- The majority of those who spend between 11-20+ hours in research per week were linked to an academic institution.

## 2) Assessment of numbers and distribution of consultants with academic appointments, hence formally linked to the university sector and whose contract generally includes time for research:

- From a total of 2,700 medical consultants in the HSE and funded hospitals, 189 had a formal joint university academic appointment in 2018. This represents 7% of the total number of consultant posts employed by model 4 and speciality hospitals.
- The percentage of clinical staff with an adjunct or honorary appointment significantly outnumbers those with a formal academic appointment (approximately 9:1).
- A total of 21 of 50 public hospitals employ consultants with an academic appointment.
- The majority of medical consultants with a formal academic appointment (CFAA) belonged to the Royal College of Surgeons in Ireland (RSCI) HG (n = 42, 22%), followed by those in Dublin Midlands HG (n = 34, 18%).
- The hospital with the largest number of consultants with an academic appointment was Galway University Hospital.
- The majority of CFAAs (69%) are based in Model 4 hospitals.
- The university with the largest number of CFAA was RCSI (25%), followed by NUI Galway, University College Dublin (UCD), Trinity College Dublin (TCD) and University College Cork (UCC), ranging between 16-19%.
- The majority of CFAA were general surgeons (13%), followed by psychiatrists (11%) and obstetricians and gynaecologists (10%). These three disciples have a disproportionately higher representation of CFAA compared with the national picture. The remaining 27 specialities were each represented by fewer than 10% of clinicians.

Activity Indicator 2

# Research Studies Undertaken

In the absence of a national register for research projects within the health service, information was gathered from alternative sources including the Research Ethics Committees (RECs), the Health Research Board (HRB), the EU participant portal, the European Clinical Trials Register (EudraCT) and the Health Products Regulatory Authority (HPRA) among others.

## 1) Studies Approved by RECs in 2017

- A total of 32 RECs were identified in the HSE and its funded organisations, all of which were asked for the titles of projects approved in 2017 for the purpose of this report.
- Title information was received from 30 out of the 32 RECs contacted. No title information but total number of proposals approved in 2017 was received from the Beaumont REC. No data was received from the Daughters of Charity REC.
- The majority of RECs submitted information for 2017, but 3 (2 of them with very small numbers) submitted information for a different year. In spite of this and given the small numbers, we believe the analysis reasonably represents annual turnover overall.
- The total number of study proposal approved by the 31 out of the 30 RECs was 1,829. As many of the studies involved multiple sites and may be reviewed by more than one REC, this number reflects an undetermined level of duplication, therefore the total number of projects reviewed by RECs in one year would be less than that.
- The region with the largest amount of RECs and of REC approvals was the East Region, with almost 678 REC approvals in 2017 (involving 20 RECs), and followed closely by the South West Region with 525 (reviewed by a single REC).
- Approximately one-quarter of all the 1,772 study proposals reviewed by the regional RECs were of Generic Health Relevance[3], followed by Cancer, Mental Health, Reproductive Health and Childbirth, Cardiovascular and Neurological Health. The studies most commonly involved Treatment Evaluation and Health Services Research.
- A national total of 75 research projects approved were specific to primary care; 57 received by the Irish College of General Practitioners (ICGP) and 18 by the Primary Care Research Committee. The majority of these were of Generic Health Relevance and most commonly involving Health Services Research.

3 Generic Health relevance refers to research applicable to all diseases and conditions or to general health and wellbeing of individuals, public health research, epidemiology and health services research that is not focused on specific conditions and underpinning biological, psychosocial, economic or methodological studies that are not specific to individual diseases or conditions.

## 2) HRB Funded Studies

- Healthcare professionals were involved in 45 (38%) HRB awards in 2017, worth a total of €44,610,369[4]. The research topics most often funded were Generic Health Relevance, followed by Cancer, Neurological, Mental Health, Cardiovascular, and Reproductive Health and Childbirth.
- 23 of these grants were awarded to 18 consultants with a joint academic appointment. The total amount of funding received by this cohort amounted to €23,093,127; which represents 29% of all HRB grants, and 52% of all HRB grants awarded to healthcare professionals. This includes funding for Clinical Research Facilities.

## 3) EU Research Grants

- There were six EU research grants awarded in 2017 which involved the HSE as a partner. The total value of these (to all the EU project partners) was €102,317,219, of which €695,245 was awarded to the HSE. The numbers of partners ranged from 13 to 109 and the majority of projects topics were of Generic Health Relevance.
- The total value of EU research funding received by the HSE in the last 10 years (from 2009 to 2019) is €2,019,069.56.

## 4) Regulated Clinical Trials

- According to the EudraCT database, a total of 27 Clinical Trials of Investigational Medicinal Products (CT-IMPs) started in Ireland in 2017, while 70 were on-going. These are a small percentage of all REC approved studies. Almost all were commercial trials for the purpose of Treatment Evaluation (92%), and 33% of those related to Cancer.
- These figures are significantly lower than European countries with a similar population; Denmark and Finland, which had 365 and 180 clinical trials respectively registered on EudraCT during the same time period.
- In 2017, seven clinical investigations of medical devices were approved by the HPRA. One had an Irish academic sponsor and the remainder were industry sponsored. Nearly half of them were clinical investigations related to devices for cardiovascular conditions. The Saolta University Health Care Group was the most common host for these clinical investigations. This may be related to the fact that CÚRAM, the Science Foundation Ireland (SFI) Centre for Research in Medical Devices is hosted in NUI Galway.

## 5) Research in the third level sector funded by the HSE in 2017

- In 2017 there were 56 research related projects commissioned by the HSE from third level institutions. This represented a total spend of €6.5 million; 32% of which was awarded to UCC. The majority of studies were of Generic Health Relevance (68%), and related to Health Services Research (62%).

4 Note funding to clinical research facilities is included in this figure.

Activity Indicator 3

# Scopus Indexed Publications, 2013-2017

Publication output was measured by the number of journal articles published in Scopus indexed journals.

- The total number of publications from HSE organisations and section 38 hospitals nationally from 2013 to 2017 was 13,466 (this includes total HSE Hospitals, n = 4,050; total Voluntary Hospitals, n = 8,934; and total Community and Non-Hospital, n = 482)
- Publication output has increased slightly year-on-year, but community and non-hospital research only account for between 3 to 4% of the total output each year.
- The total number of journal articles published nationally in 2017 was 2,975. This was comparable to the total publication output (all disciplines) of universities such as TCD or UCD in 2017 (excluding publication output of university-associated institutions).
- St James's Hospital (SJH) was the hospital with the largest publication output in 2017, followed by Beaumont Hospital and St Vincent's University Hospital (SVUH).
- Dublin Midlands HG and Ireland East HG had the highest number of publications but the Children's HG showed the highest publication ratio (publication output divided by the total number of staff in the HG).
- As the majority of publications were from staff affiliated with hospitals, the distribution of the research topics at national and hospital level were identical: the top research topics were Generic Health Relevance[5] (17%), followed by Cancer (15%), Cardiovascular (9%), Neurological (8%) and Reproductive Health and Childbirth (7%) research. Treatment Evaluation represented nearly half of the total research activity of publications in 2017 (43%), followed by Aetiology (27%), Health Services (14%), Detection and Diagnosis (8%) and Disease Management (3%).
- A different profile of publication topics was observed for community and non-hospital based research, where the majority of publications related to Mental Health (27.9%), followed by Generic Health Relevance (23%), Infection (10%), Cancer (7%) and Neurological (5%). Treatment Evaluation represented over half of the total research activity of publications in 2017 (54%).
- Of the total 13,466 articles published between 2013 and 2017 within the Irish public health system, 4,964 (37%) were published by consultants with a formal academic appointment. This indicates that the publication output of this cohort is very prolific as they represent only 7% of the total number of existing consultants. It also indicates that 63% of the publication output is produced by staff without a formal university appointment.

5 Generic Health relevance refers to research applicable to all diseases and conditions or to general health and wellbeing of individuals, public health research, epidemiology and health services research that is not focused on specific conditions and underpinning biological, psychosocial, economic or methodological studies that are not specific to individual diseases or conditions.

Activity Indicator 4

# Clinical Research Networks

For the purpose of this report, Clinical Research Networks are defined as networks of clinicians with an interest in a particular disease or topic who are devoted to the improved care of patients and health services through research in that particular topic. Clinical Research Networks indicate the existence of a critical mass of research activity around a specific disease. Some of these networks often involve other actors such as academics, scientists, patients, professional bodies, etc. We divided clinical research networks into two types: Clinical Trial Networks (focused on clinical trials of medicinal products, clinical investigations of medical devices and other clinical research studies) and Collaborative Clinical Research Networks (focused on improving understanding and the sharing of knowledge and research expertise).

## Clinical Trial Networks

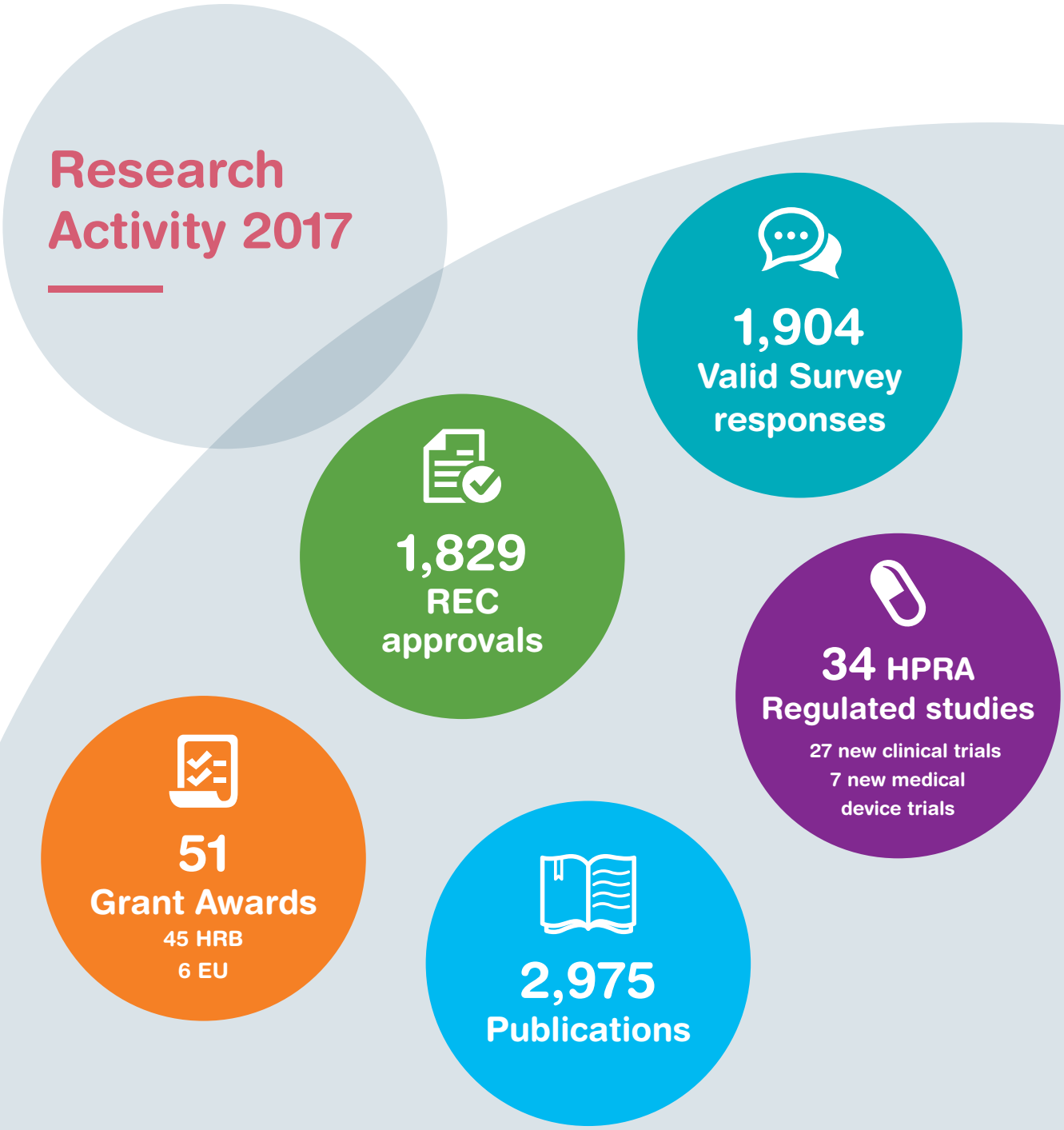
- We defined Clinical Trial Networks as those with a focus on clinical trials of medicinal products, clinical investigations of medical devices and other clinical research studies.
- There are 10 Clinical Trial Networks in Ireland, many of them funded by the HRB, and these conduct the vast majority of trial activity in Ireland.
- There are a number of networks and organisations that support the conduct of multicentre clinical trials (both commercial and academic) across Ireland, including HRB Clinical Research Coordination Ireland (HRB-CRCI), HRB Trials Methodology Research Network (HRB-TMRN) and Cancer Trials Ireland (CTI).
- Cross-border Healthcare Intervention Trials in Ireland Network (CHITIN) is a new cross-border initiative aimed at promoting healthcare intervention trials to prevent and cure illness, and to promote improved health and wellbeing in Northern Ireland, Ireland and Irish cross-border areas.
- As per 2018, there are seven Clinical Research Facilities/Centres (CRFs/Cs) jointly associated with universities and their associated university hospitals, and 14 Oncology Clinical Trials Units associated with CTI.

## Collaborative Clinical Research Networks

- Collaborative Clinical Research Networks are clinician-led and focus on improving understanding and the sharing of knowledge and research expertise. This report highlights five of them, although this is a non-exhaustive list.

# In summary this study shows

A significant percentage of staff in the HSE and its funded organisations are research active, and the outputs cannot be underestimated. Despite the fact that research is by and large not formally embedded within the process of service delivery, it is very much a part of the on-going activity in the health and social care service, and it cannot be ignored. The data in this study shows the huge potential for impact that could be leveraged by aligning the research activity to service needs, in order to obtain the maximum benefit for our health service and the health and wellbeing of our patients and the general population.



# 1. Introduction and Context

Health research contributes to the advancement of scientific knowledge and the evidence base. The utilisation of this evidence is essential to improve the health and wellbeing of patients, to improve health service delivery and the equity of healthcare provision. Evidence has shown that research-active organisations deliver better patient outcomes, including reduced mortality rates[6] and a growing body of evidence indicates that healthcare organisations with a strong research culture deliver better care. Such a culture is associated with better organisational performance, reduced staff turnover, improved patient satisfaction and improved organisational efficiency, and these benefits go beyond those experienced directly by research participants.[7] Furthermore, the economic benefits of health research cannot be underestimated; a briefing document published in 2014 by the Wellcome Trust[8] in the UK indicates that each pound invested in cancer-related research by the taxpayer and charities returns around 40 pence to the UK every year thereafter.

Research will therefore be central to achieving the desired reform of the Irish health system over the coming years, since transformation of the way in which healthcare is delivered, managed and financed will require high quality clinical, population health, and health services research.

In 2018 the HSE established the HSE Research and Development (R&D) function. This new function aims to ascertain what is required to embed research as part of the cultural fabric of health service delivery and to take the steps to ensure that this becomes a reality in the medium to long-term future. In order to inform the future work of this function and to deliver on one of the HSE objectives articulated in the Government's Action Plan for Health Research 2009-13, an assessment of the existing level of research activity in the HSE and its funded organisations was carried out. This will represent a benchmark against which future progress can be measured.

For the purpose of this report, research is defined in accordance with the UK Research Governance Policy Framework as **"the attempt to derive generalisable or transferable new knowledge to answer or refine relevant questions with scientifically sound methods"**. It refers to research that takes place in the HSE and its funded organisations, and that involves their patients, data, staff or infrastructure. This includes:

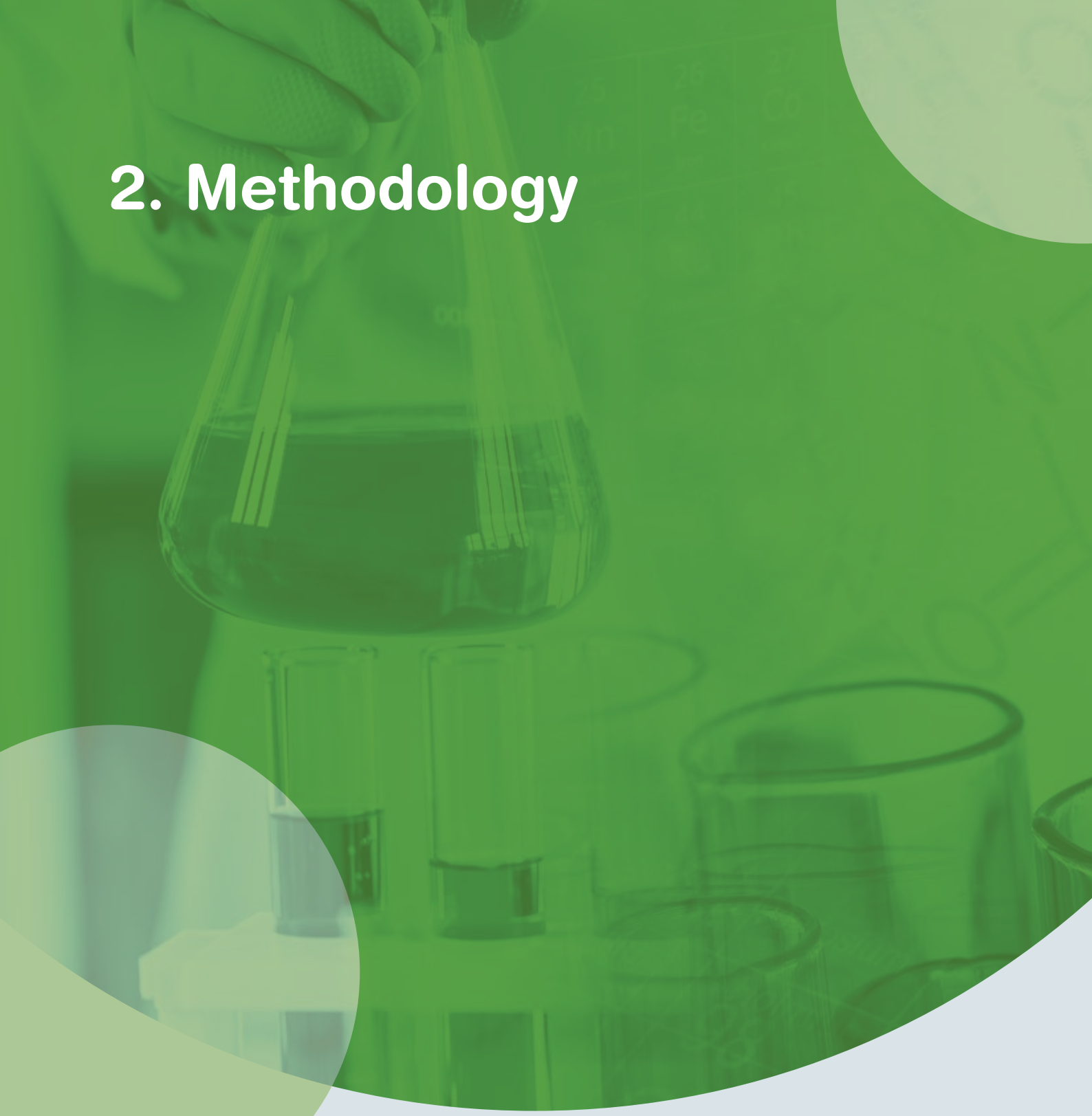
- activities that are carried out in preparation for, or as a consequence of, the interventional part of the research, such as screening potential participants for eligibility, obtaining participants' consent and publishing results,
- non-interventional health and social care research (i.e. studies that do not involve any change in standard treatment, care or other services),
- studies that aim to generate hypotheses, methodological research, and descriptive research,
- studies whose primary purpose is educational to the researcher, either in obtaining an educational qualification or in otherwise acquiring research skills, which also fall into the definition of research.

Projects that are not strictly research according to the definition (e.g. standard service evaluations) are often reviewed and approved by research ethics committees and published. It was therefore not possible to exclude these related activities from some of the datasets and consequently some of this activity is included in the analysis presented in this report.

6 Ozdemir BA, Karthikesalingham A, Sinha S, Poloniecki JD, Hinchliffe RJ, Thompson MM, Gower JD, Boaz A and Holt PJE. Research Activity and the Association with Mortality. *PLOS ONE* 2015, **10**(2):e0118253. https://doi.org/10.1371/journal.pone.0118253

7 Harding K, Lynch L, Porter J, Taylor NF. Organisational benefits of a strong research culture in a health service: a systematic review. *Australian Health Review* 2016, **41**(1)45-53. https://doi.org/10.1071/AH15180.

8 The 2014 Medical Research: What's it worth? Study by RAND Europe, the Health Economics Research Group at Brunel University and King's College London; and commissioned by the Academy of Medical Sciences, Cancer Research UK, the Department of Health and the Wellcome Trust. www.wellcome.ac.uk/economicbenefitscancer



# 2. Methodology

## 2.1. Research Activity Indicators and Associated Datasets

In order to assess research activity in the HSE and associated organisations, four key activity indicators were used:

- staff involved in research
- research studies undertaken
- publication outputs
- Clinical Research Networks

The lack of comprehensive datasets and difficulties accessing existing datasets were significant impediments for this study. However, while the information available was limited and imperfect, it has enabled us to paint the first picture of this kind and has highlighted the gaps in information management that need to be addressed to repeat this exercise in the future in a more substantial way. The problems encountered and alternative approaches used are outlined in Table 1.

**Table 1: Key research activity indicators**

| Key Activity Indicator | Impediments | Approach |
|---|---|---|
| **Staff involved** | • Involvement in research is often a partial occupation, not formally recorded as part of the HR process for the different health service professions.<br>• Full-time researchers are hired under other HR grades (i.e. Administration) and are therefore impossible to quantify using HR systems.<br>• Association of clinical staff with universities via honorary or adjunct positions is not formally tracked by the HSE. | • A national survey was used to capture data on self-declared research active staff.<br>• HR data was used to assess the numbers of clinical staff with formal academic appointments. |
| **Research Studies undertaken or commissioned** | • The health service is delivery focused; research activity is not measured, therefore it is not systematically recorded: there are no national or local research information systems or protocols to record research activity.<br>• Funded studies are not registered in the financial systems as the funding is generally managed by external organisations (i.e. universities, foundations, etc.). | • Most Research Ethics Committees in the health service provided information on research studies reviewed.<br>• The Health Research Board was approached for information on funded research studies that involved health service staff in a Principal or Co-principal Investigator capacity.<br>• Information on EU funded studies in which the HSE was a participant was obtained from the EU participant portal.<br>• Research Offices in Universities and HEIs provided information on HSE commissioned studies.<br>• Information on regulated clinical trials in Ireland was obtained from the EU Clinical Trials Database.<br>• The HPRA provided information on regulated clinical investigations. |

| Key Activity Indicator | Impediments | Approach |
|---|---|---|
| **Publication Output** | • Some health professionals linked to universities publish their research outputs using only their university affiliation.<br>• Much of the research activity does not get formally published in peer-reviewed publications but rather in the form of reports published at local level. While some of these outputs are published in the Lenus Open Access repository of the HSE National Health Library and Knowledge Service, it was not possible to determine if these were the result of research activity or not, and therefore could not be included in this study. | • Publications indexed in Scopus were analysed using the SciVal analysis tool. These included all indexed publications (journal articles, books, book chapters, etc.).<br>• Publications of staff with a formal academic appointment were available via Scopus. |
| **Clinical Research Networks** | • Lack of specific definitions.<br>• Many networks are associated with the University sector with a more academic focus making it difficult to classify the information available. | • Information was obtained from CRDI and the HRB. Internet accessible information was also obtained and validated via telephone calls. |

A further description of each dataset used is provided in each chapter.

## 2.2. Time periods

While the original intention of this study was to ascertain research activity within the last five years this was generally not possible due to the nature of the datasets and the limitations of data availability. The following time-periods were analysed for the different indicators:

### a) Staff involved: 2018

- Survey of staff self-identifying as being involved in research as per June 2018.
- Staff with a formal academic appointment as per February 2018.

### b) Research studies undertaken: 2017

- The data available from the different data sources was originally available for different time periods. In order to simplify the information for this report and to use a consistent approach across the datasets to enable comparisons, only data for 2017 has been included in this study.

### c) Publication output: 2013-2017

- Publication output was analysed for a five year period, from 2013 to 2017. There is generally a time-lapse between the research being performed and the output being published; therefore it is not possible to relate this dataset to any of the above.
- To enable a more comprehensive understanding of the types of Irish health research being published in Scopus-indexed journals, an in-depth classification and analysis of the 2017 publications was conducted.

### d) Clinical Research Networks: 2018

- The Clinical Research Networks identified were in existence as per 2018.

## 2.3. Classification Methodology

In order to analyse the datasets associated with research studies and publication outputs, the data was categorised using the UK Health Research Classification System (HRCS)[9] developed in 2005. Two dimensions of the framework were used for this study:

- 21 Health Categories, denoting the area of health or type of disease being studied (e.g. cancer, mental health, reproductive health and childbirth, etc.).
- Eight top-level research activity codes denoting the type of research being conducted (e.g. treatment evaluation, health services research, etc.).

This methodology has also been used by the Health Research Board (HRB) in Ireland to classify HRB funded research.[10, 11] A detailed breakdown and description of the categories is available in Appendix 1.

9 Health Research Classification System, February 2018. Medical Research Council on behalf of the UK Clinical Research Collaboration. ISBN 978-0-903730-27-3.

10 Curran B and Barett R (2014). Outputs, outcomes and impacts arising from the HRB's 2000-09 grants portfolio. Health Research Board, Dublin.

11 Hiney M (2018). A study of activity from 2011 to 2015 using the Health Research Classification System. Health Research Board, Dublin.

# 3. Activity Indicator 1: Health Service Staff involved in Research

The following section focuses on the staff conducting research within the public health and social care service. Many of these would be the staff members involved in the research studies referred to in Section 4, those responsible for publishing the outputs referred to in Section 5, and members of the networks described in Section 6. This activity indicator was explored by way of two approaches:

1. Analysis of information from self-declared research engaged staff working in the HSE and its funded organisations, which was captured by way of a national survey launched in June 2018. The survey was distributed via a number of channels including email broadcasts and targeted mailing lists of professional associations and networks, via social media and through the HSE website.
2. Analysis of information related to medical consultants with a university academic appointment for the purpose of research and teaching.

## 3.1. Survey of Research Active Staff

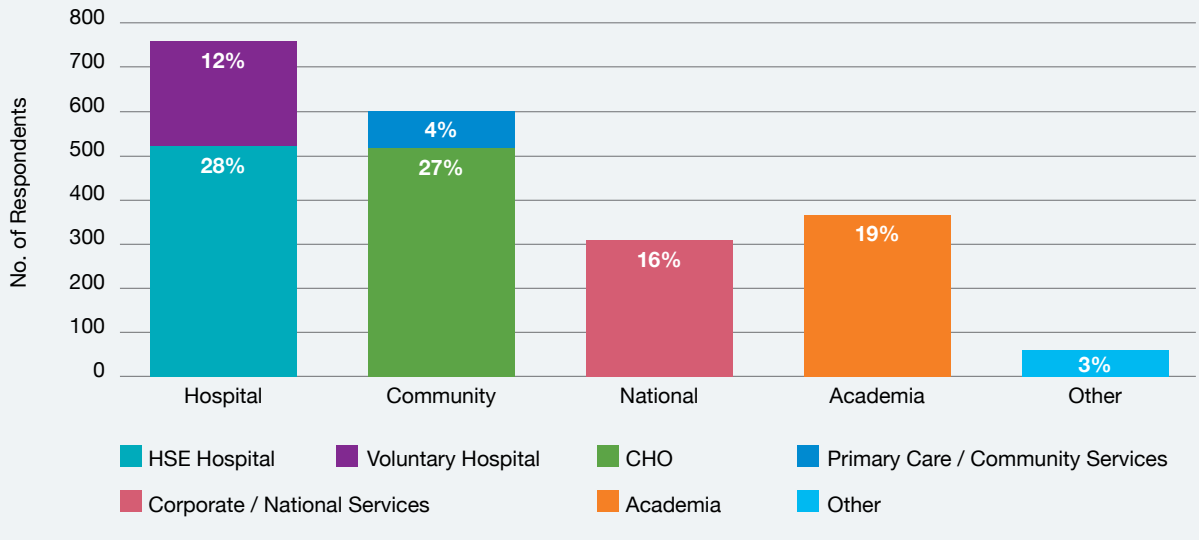
A total of 1,920 respondents completed the survey, but 16 indicated that they worked in the private healthcare sector, so their responses were removed from the dataset. The results below represent an analysis of the information provided by the **1,904 respondents.** It should be noted that the results must be interpreted in the context of responses to the survey, rather than as absolute numbers.

### 3.1.1. Survey Analysis by Place of Work

The responses indicated that **staff were engaged in research in all areas of the service, including the acute and community sectors, as well as national services and HSE corporate, and many were also linked to academia** (Figure 1). Respondents were able to select more than one place of work, with some selecting up to six. In total, 11% indicated more than one place of work.

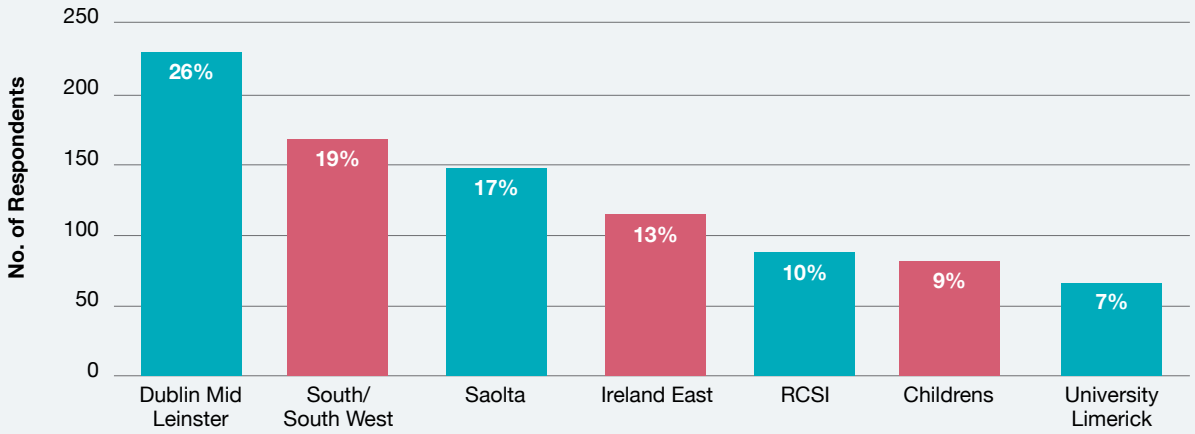
Of the 1,904 respondents, **40% worked in acute hospitals, 31% worked in the community, 16% worked in national services, programmes or HSE corporate, 19% worked in academia and 3% in other areas of the service** (Figure 1).

Figure 1: Place of work of respondents (indicated as number and percentage of the total sample)



From the subset of hospital-based staff, **31% of hospital respondents worked in voluntary hospitals and the remaining 69% were based in HSE hospitals**. This matches the general distribution of public hospitals, whereby 32% (16 out of 50) are voluntary hospitals. All hospital groups (HG) were represented in the response (Figure 2), and **the Dublin Midlands Hospital Group was the one with the largest percentage of respondents (26%)**.

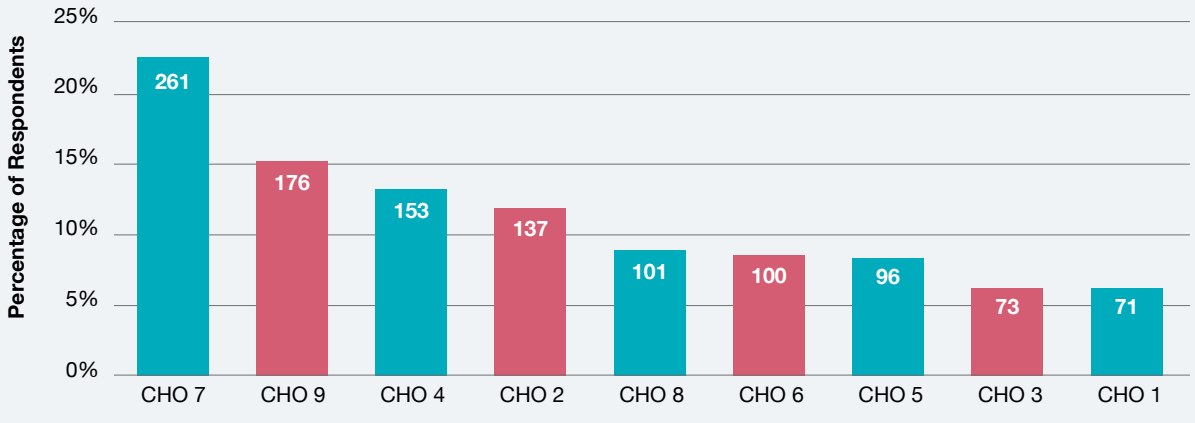
Figure 2: Number (including percentage) of research active respondents from each hospital group




Hospital groups vary greatly in their size (number of hospitals per group, and number of staff per hospital). In order to make a more meaningful comparison, the number of responses per hospital group was divided by the total staff number from each hospital group, including both clinical and non-clinical staff to calculate response rates. From this perspective, **the largest proportional response rate was from the National Children's Hospital Group, followed by the Dublin Midlands Hospital Group.**

Analysis of the Community Health Organisation (CHO) distribution of respondents indicated that the **majority of respondents (22%) were in CHO 7** (Figure 3). As with hospital groups, the geographical area of CHOs as well as their total staff number, varies greatly. Again, in order to make a more meaningful comparison, the response rate was calculated as a ratio between the total number of responses per CHO and the total number of staff in each CHO. This still showed that **the largest proportional response rate was in CHO 7.**

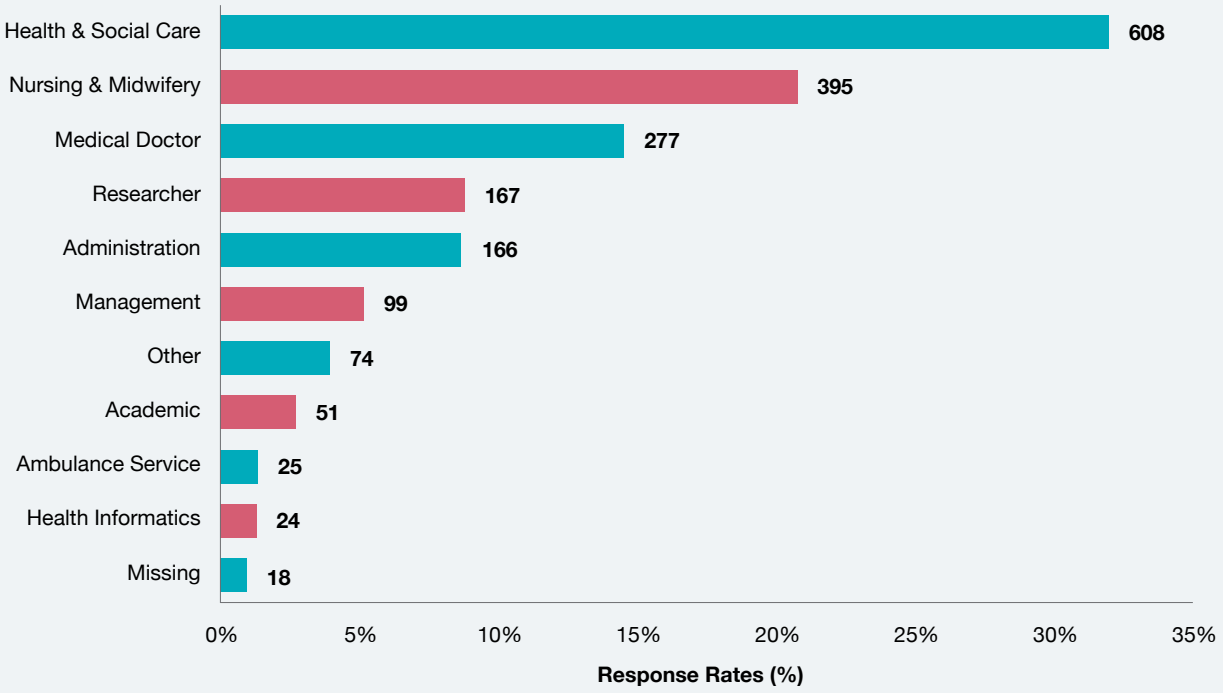
Figure 3: Percentage (including number) of respondents by CHO



### 3.1.2. Survey Analysis by Profession

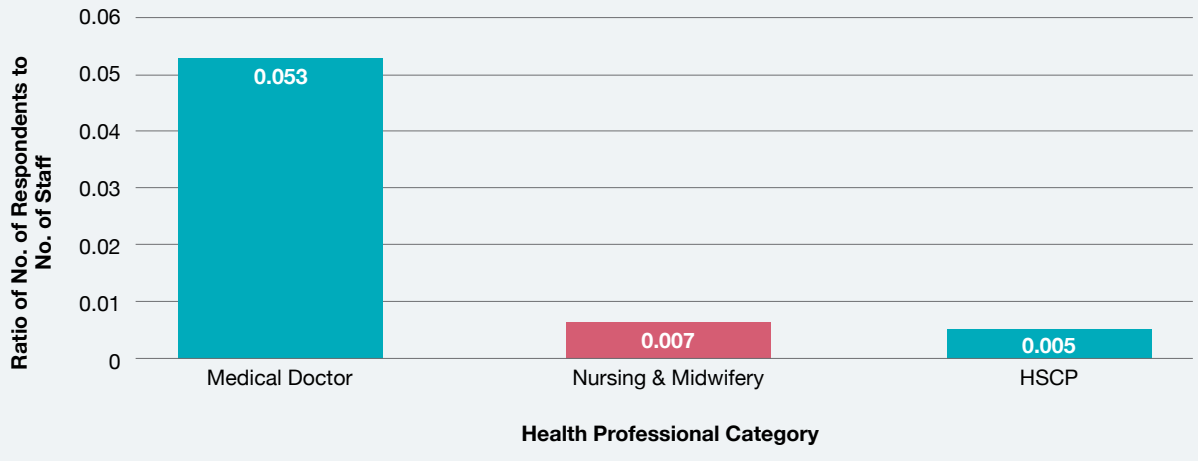
Analysis by profession (Figure 4) indicated **that the majority of the respondents belong to the Health and Social Care professions**[12] **(32%) closely followed by Nursing and Midwifery (21%) and Medical Doctors (15%)**.

Figure 4: Percentage (including number) of respondents by profession




Staff numbers in each of these categories vary greatly at national level however, so the results were normalised by the total number of professionals per group for the clinical categories (medical, nursing/ midwifery and HSCP) and this indicated that **medical doctors were overwhelmingly the most research active** (Figure 5).

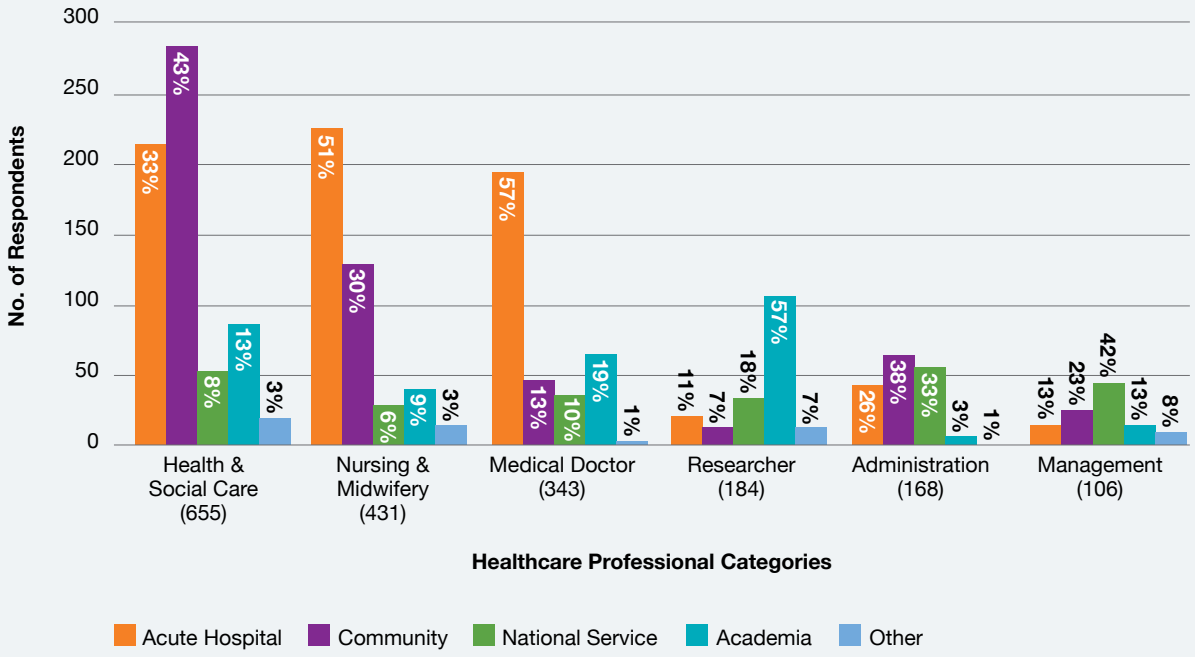
Figure 5: Responce ratio (total number of respondents per category by total number of staff in that category) by profession




12 HSCP refers to the 14 designated health and social care professions: Clinical Biochemist, Dietitian, Dispensing Optician, Medical Scientist, Occupational Therapist, Optometrist, Orthoptist, Physiotherapist, Podiatrist, Psychologist, Radiographer, Social Care Worker, Social Worker, Speech and Language Therapist.

**The majority of doctors and nurse/midwifery respondents were based in acute hospitals, while the majority of HSCPs respondents were based in community settings** (Figure 6).

Figure 6: Number (including percentage) of staff in research by profession and health service area (or location)




## 3.1.3. Survey Analysis of Educational Qualifications

Survey respondents were asked about their highest academic qualification. **Clinical staff categories (medical doctor, HSCP, nursing/midwifery) had higher qualifications than non-clinical staff** (Figure 7). The highest most commonly occurring qualification level, across the three main clinical professional groups was a master's degree (Figure 8), with the percentages listed representing the proportion of each qualification within each professional group: **48% of all nursing and midwifery respondents had a master's degree,** and **medical doctors and HSCPs respondents had the highest proportion of PhDs (23% and 22% respectively)**.

Figure 7: Number (including percentage which represents the proportion within the Clinical and Non-Clinical grouping) of respondents by highest qualification level

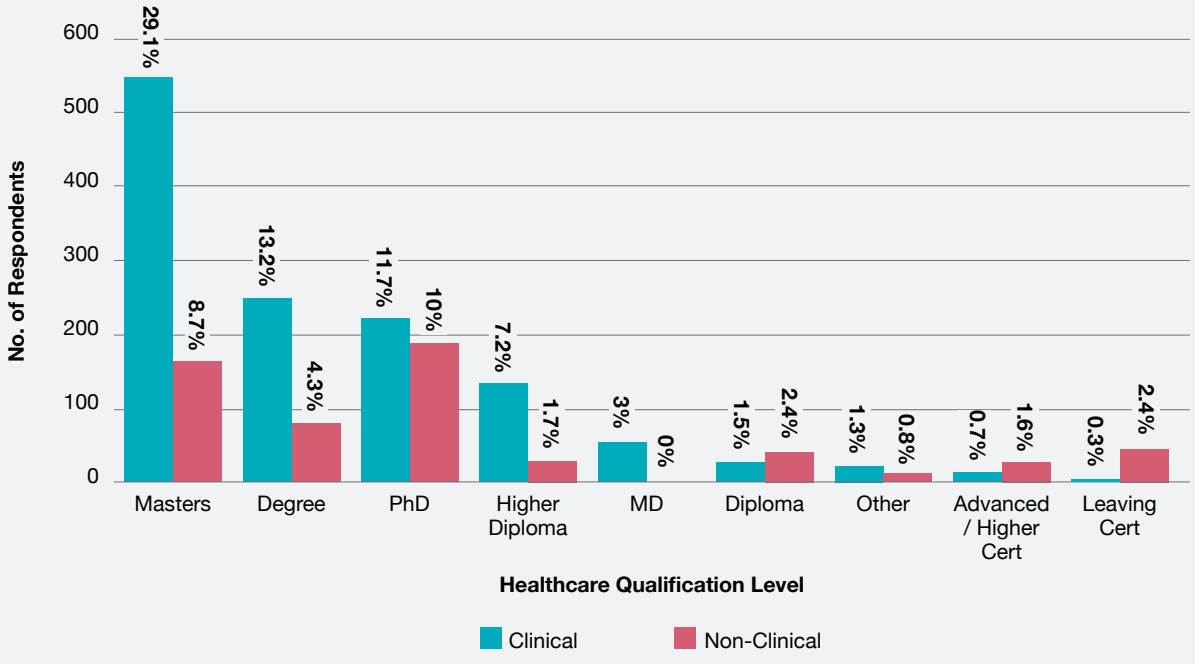
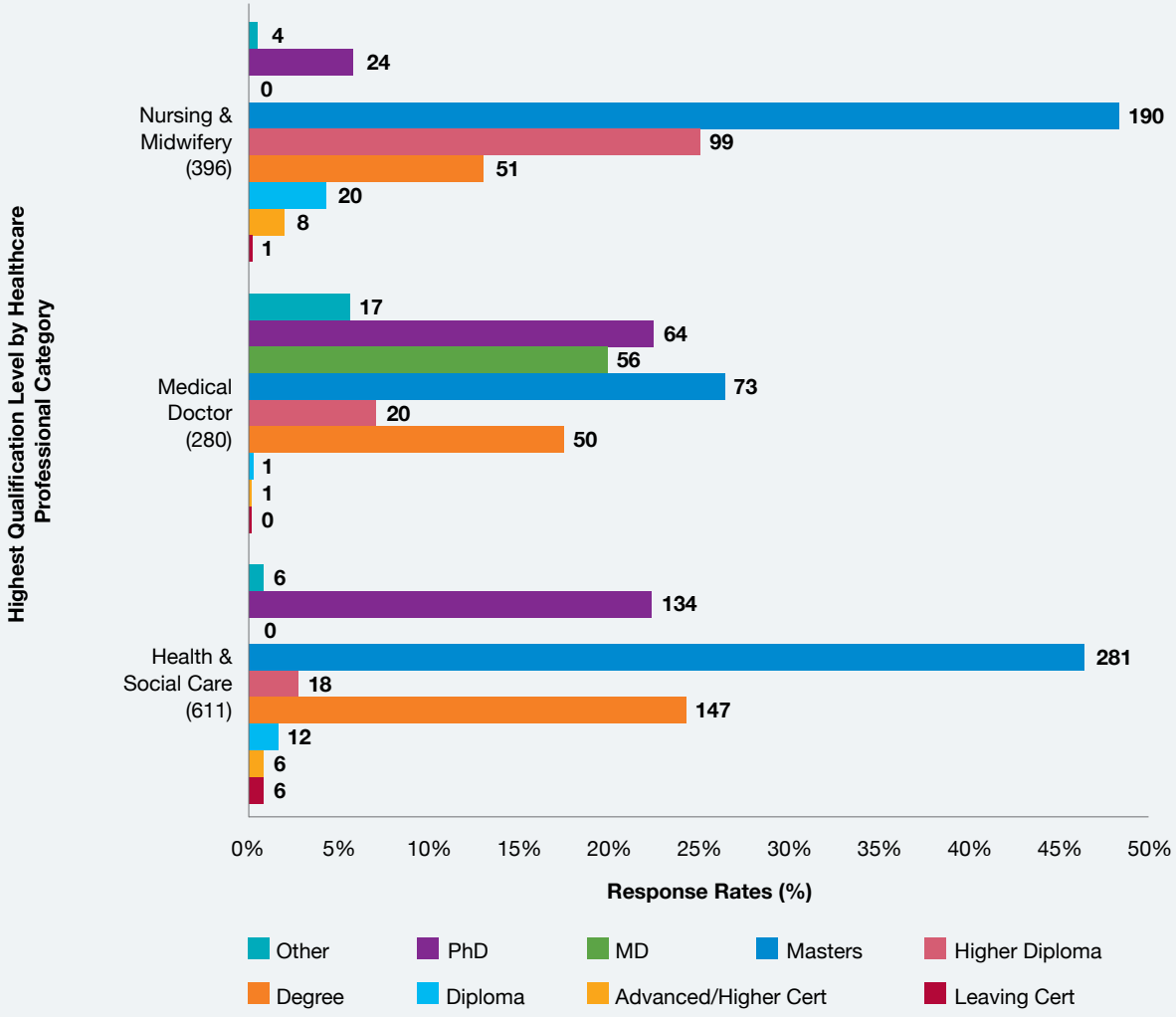



Figure 8: Percentage (including number) of clinical staff by highest qualification level



### 3.1.4. Survey Analysis of Researcher Competencies

Respondents were asked to pick the description that best described their research competencies or their involvement in research as indicated in Table 2.

**Table 2: Self-reported research competencies**

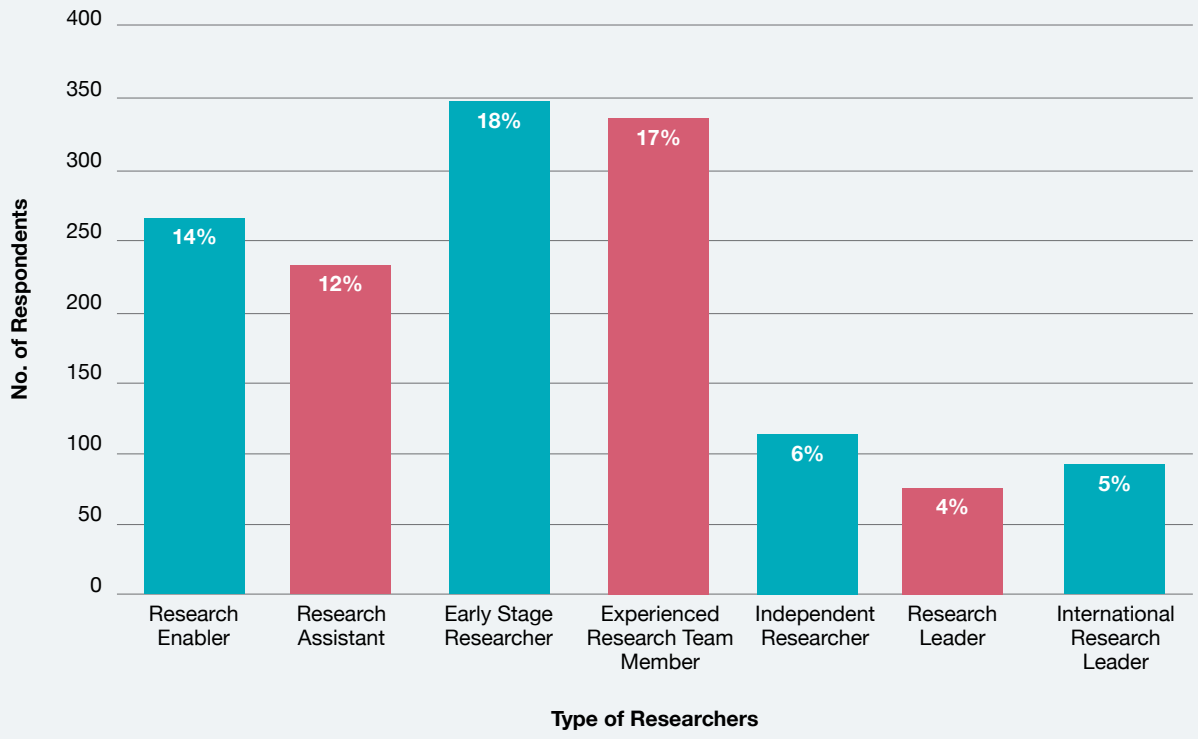
| Researcher Category | Research Competencies |
|---|---|
| Research Enabler | • I do not actively participate in the collection, analysis or reporting of data<br>• I generate research ideas, identify research needs and appropriate people to undertake this body of work<br>• I have contributed to design and research grant applications when requested<br>• I commission research |
| Research Assistant | • I contribute to a wider research team by carrying out data collection<br>• I organise access to data<br>• I clean and prepare data for use in analysis<br>• I conduct literature searches |
| Early stage researcher | • I carry out research under supervision, demonstrating the ability to collect, analyse and interpret data<br>• I can critically evaluate and synthesise new information<br>• I have excellent communication skills and am able to communicate the outcomes of my research |
| Experienced Research team member | • I design and implement research studies<br>• I present my research at conferences either orally or by poster<br>• I manage a research project and contribute to grant applications<br>• I have produced a substantial body of work that merits publication in peer-reviewed journals |
| Independent researcher[13] | • I design and implement research as part of a wider research programme<br>• I apply for research grants<br>• I manage and supervise a team of research staff<br>• I mentor research staff and contribute to articles in high-quality peer-reviewed journals<br>• I present research nationally / internationally |

13 Independent researchers, research leaders or international research leaders may be carrying on their research activity under the auspices of the HSE or associated organisation such as a university.

| Researcher Category | Research Competencies |
|---|---|
| Research Leader | • I design and implement a substantial programme of research, including management of a research team, grant applications and financial management<br>• I have a track record of publishing in high-quality peer-reviewed journals as first author and present research internationally<br>• I have teaching experience based on my own research with a track record of mentoring research staff<br>• I have a thorough understanding of the research environment nationally and internationally |
| International Research Leader | • I have an international reputation based on research excellence<br>• I make a substantial contribution to my field or multiple areas<br>• I identify and execute research activities and lead a research team<br>• I recognise the broader implications of my research and contribute to the strategic vision for future research in my field<br>• I publish and present influential papers and books, serve on conference organising committees and deliver invited talks |

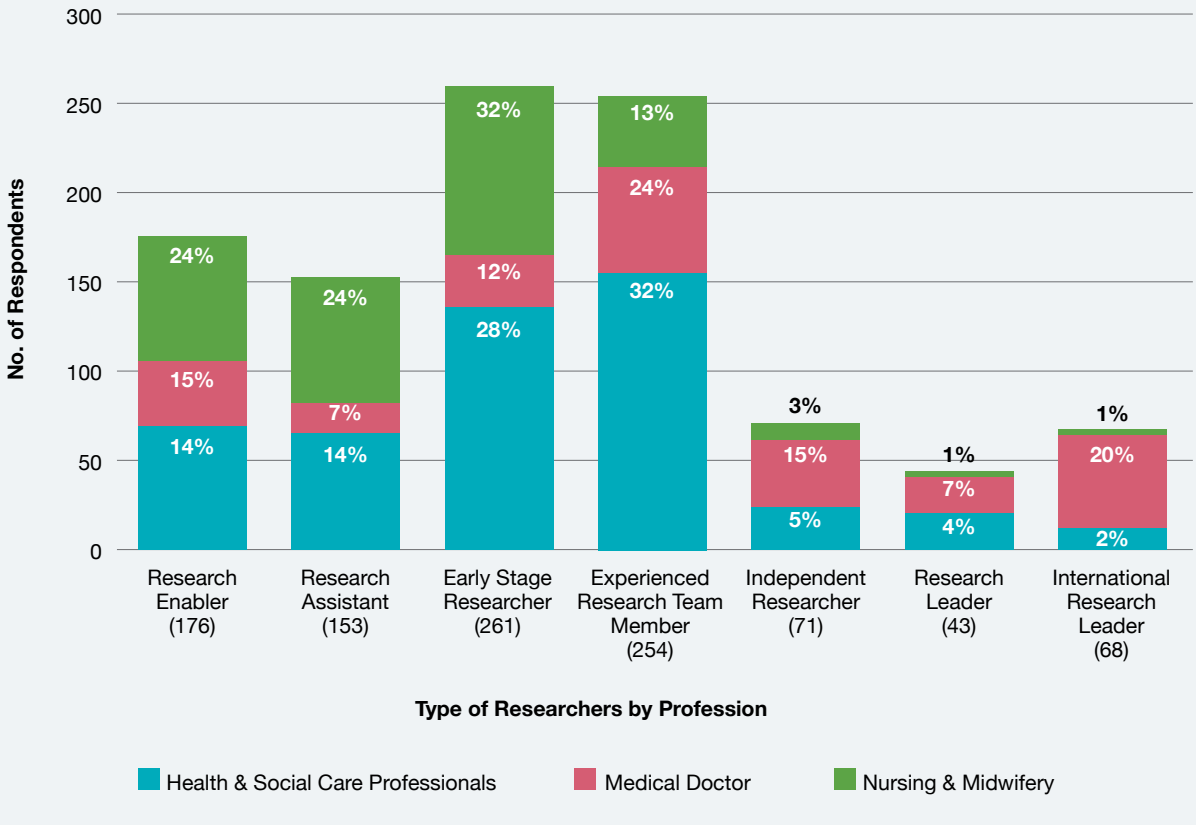
The categories of independent researcher, research leader and international research leader describe staff capable of carrying on research activity without supervision (i.e. **independent research activity**) and these three **represented a total of 15% of the respondents** (Figure 9).

Figure 9: Number (including percentage) of respondents by research competencies



Respondents from the HSCP group are represented across all categories (Figure 10), but are predominantly in the early stage and experienced research team member categories, while **a total of 11% of HSCP respondents describe themselves as being engaged in independent research activity** (independent researcher, research leader and international research leader). Medical doctors were also represented across all categories, but with more respondents classifying themselves as having the competencies of an international research leader compared with HSCPs or nurses. In total, **42% of medical doctor respondents described themselves as being engaged in independent research**. The response of **nurses and midwifery professionals** indicated that they were more predominantly involved in **enabling and assisting research activity, and as early stage researchers. HSCP respondents were more commonly in the early stage researcher and experienced research team member categories.**

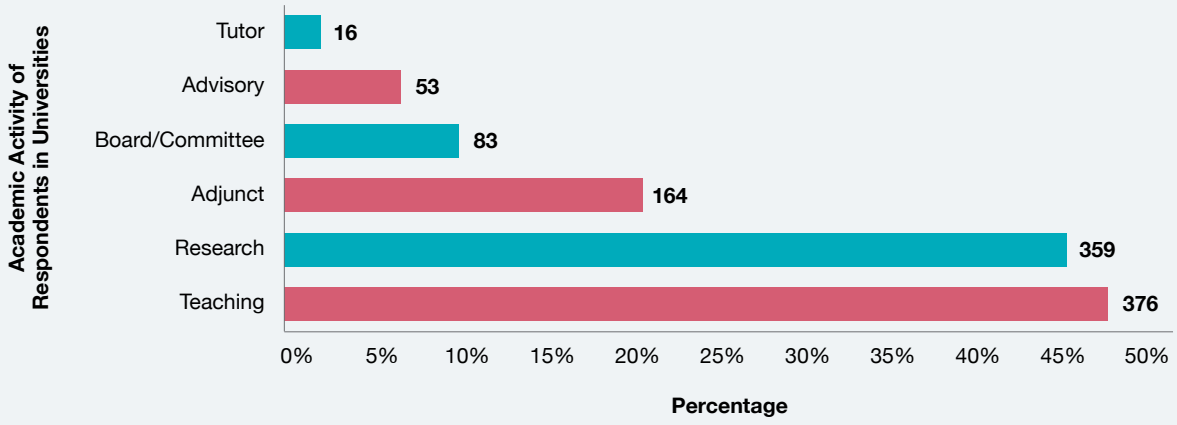
Figure 10: Number (including percentage which represents a proportion within the HSCP, Medical and Nursing groups) of respondents by type of researcher and profession (clinical types)



### 3.1.5. Survey Analysis of Responses from Staff linked with HEIs

Respondents were asked if they held a position with academic institutions: **60% indicated that they were not associated with a third level academic institution, while 40% indicated an association with the third level sector, either contractually bound or not.** The types of activities carried out in the Higher Education Institutions (HEIs) are described in Figure 11.

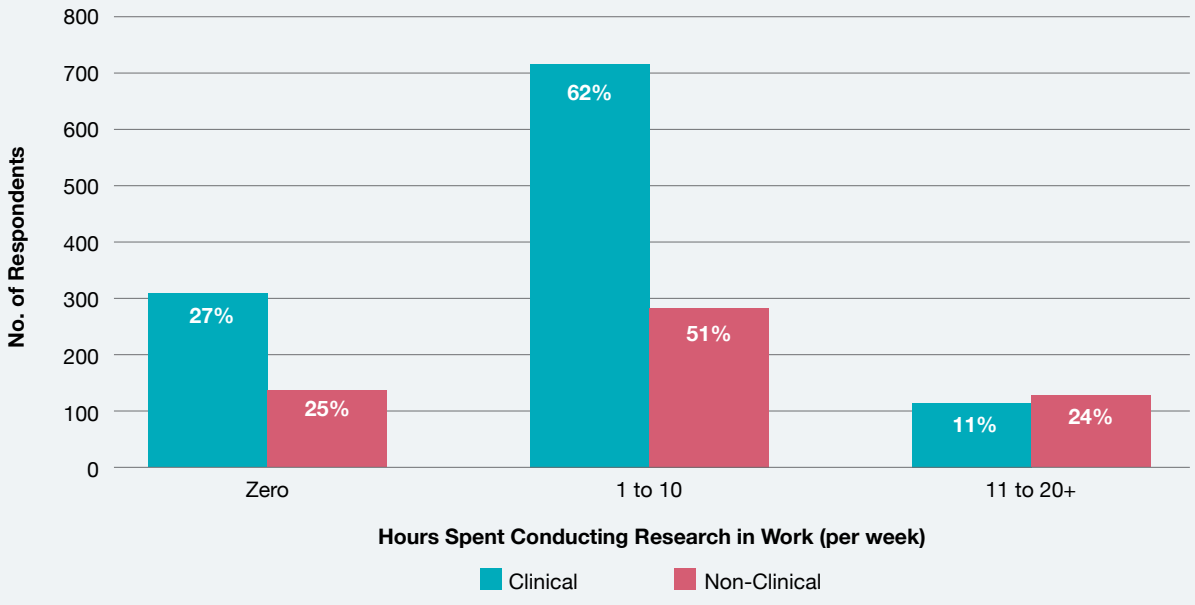
Figure 11: Percentage (including numbers) of respondents by their academic activities in HEIs




### 3.1.6. Survey Analysis of Time Available to Conduct Research

The survey sought to determine how many hours (in a typical week) respondents spend on research (Figure 12), and the results showed that **the vast majority of respondents spent between one and ten hours per week conducting research during working hours** (clinical[14] n = 728, 62%, non-clinical n = 292, 51%).

Figure 12: Hours spent on research during the working week by the number of respondents (percentages represent proportion within the clinical or non-clinical grouping)

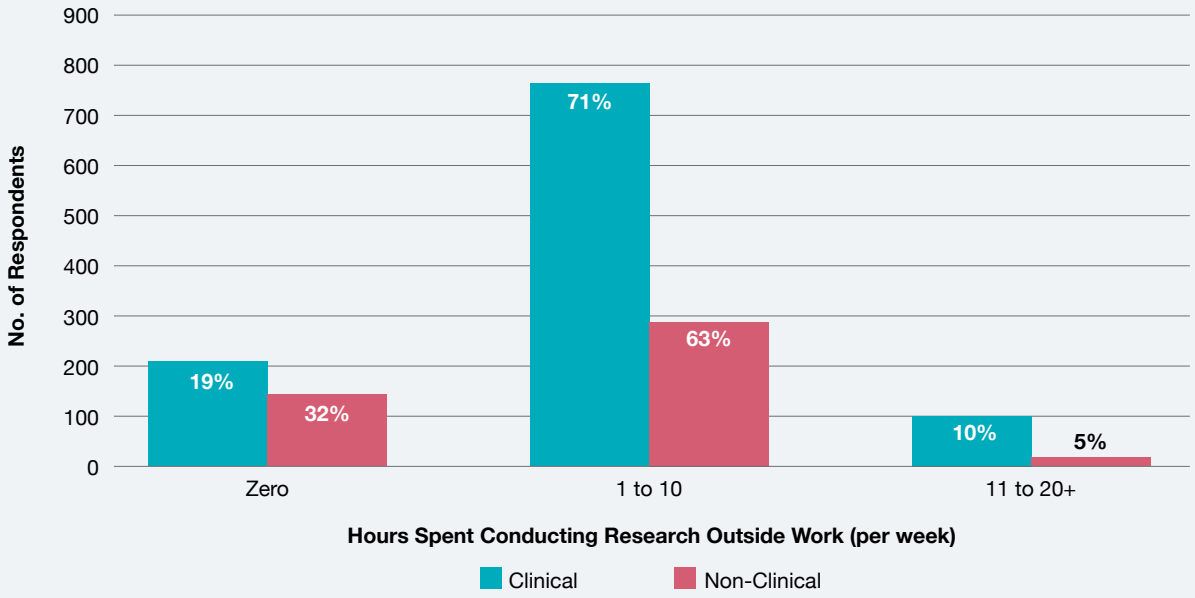



14 Clinical refers to HSCP, medical doctors and nursing and midwifery professionals. Non-clinical refers to all other professions.

Many indicated their involvement in research activity outside of working hours. Of these, 71% of clinical staff (n = 763) and 63% of non-clinical staff (n = 287) spent one to ten hours, while 10% of clinical staff reported spending between 11 and over 20 hours conducting research after formal working hours (Figure 13). **27% of clinical staff and 25% of non-clinical staff carry out research exclusively outside working hours.**

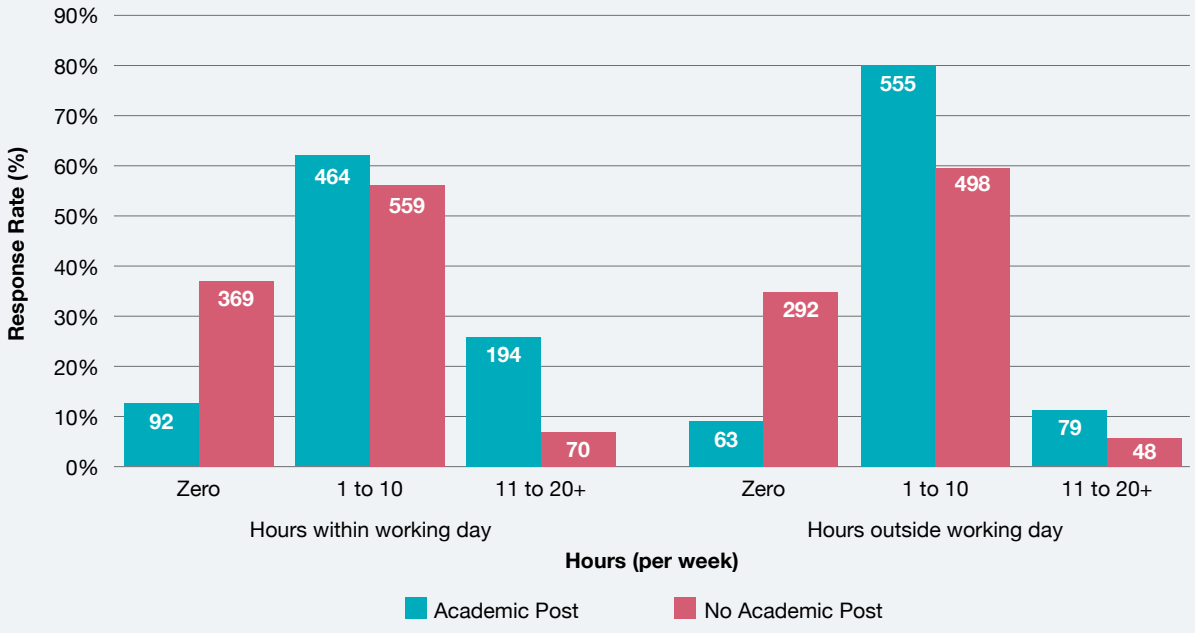
Only staff members engaged in research were asked to participate in the survey. Therefore it is assumed that those indicating "zero" during working hours were engaged in research outside working hours.

Figure 13: Hours spent on research outside of working hours by the number of respondents (percentages represent proportion within the clinical or non-clinical grouping)




Further analysis indicated that **the majority of those who spend between 11-20+ hours in research had an academic link** (Figure 14).

Figure 14: Hours spent on research inside and outside of working hours (percentages represent the proportion of respondents with and without an academic post)



## 3.2. Medical Consultants with a Formal Academic Appointment

Health professionals involved in research often have close links with the university sector. Some of those linkages involve a formal contractual academic appointment generally for the purpose of education and/or research (Section 3.1.5). In general, staff members with formal academic appointments have protected academic time, full access to support and resources offered by the third level institution, and further opportunities to establish academic collaborations.

On the other hand, there are many other healthcare staff who are non-contractually engaged with academic institutions, but who have adjunct or honorary connections. These provide formal university acknowledgement of their contributions to academic activities, recognising that many contribute strongly despite having no protected academic time, although the range of university supports offered to this cohort varies greatly.

The academic affiliation/s and key discipline of **medical consultants with academic appointments (CFAA) as per 2018** were analysed in order to determine how these staff are distributed across clinical sites and how this varies by speciality. Many medical consultants with a formal academic appointment had appointments with more than one hospital. For the purpose of the report, the analysis was based on the principal clinical site and does not include vacant posts.

Unfortunately, data on medical consultants with honorary/adjunct academic appointments was not available or not provided to us by some of the universities. However, information received from two universities [Trinity College Dublin (TCD) and University of Limerick (UL)] seems to indicate that **the percentage of clinical staff with an adjunct or honorary appointment significantly outnumbers those with a formal academic appointment (approximately 9:1).**

### 3.2.1. Distribution of Medical Consultants with Academic Appointments by Location

**In 2018 there were 189 CFAAs. A total of 21 out of 50 public hospitals (42%) in Ireland employ consultants with an academic appointment. The breakdown of CFAA posts by hospital group (based on principal clinical site) is shown in Figure 15** ('Other' indicates a non-hospital appointment). The majority of CFAAs belonged to the RCSI hospital group **(n = 42, 22%)**, followed by the Dublin Midlands hospital group **(n = 34, 18%)**. Table 3 shows the breakdown of dual appointments according to hospital within the various hospital groups.

Further analysis indicated that **the majority of CFAAs (69%) are based in Model 4 hospitals** (hospitals providing 24/7 acute surgery, acute medicine, critical care, tertiary care and, in certain locations, supra-regional care). Of the Universities, **Royal College of Surgeons Ireland (RCSI) had the larger number of CFAA posts (n = 47, 25%), with Galway (NUIG), UCD, TCD and UCC having between 16% and 19%** (n = 30 to 34).

Figure 15: Number (including %) of CFAA posts by Hospital Group (based on principle clinical site)

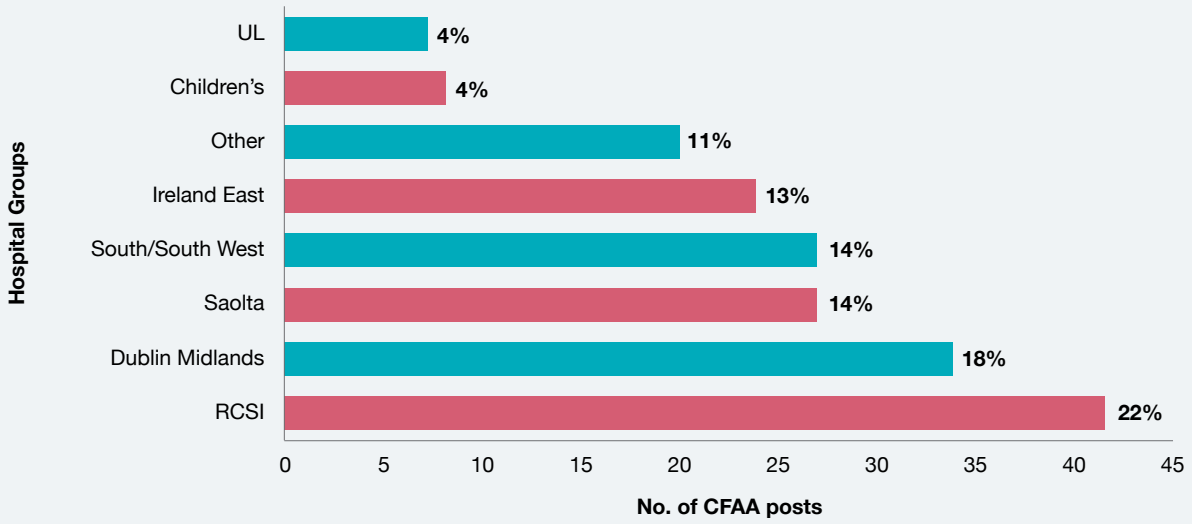



Table 3: Distribution of CFAA posts per Hospital Group and Hospitals (only hospitals with CFAA posts are shown)

| Hospital Group | Hospital | No. of CFAA posts |
|---|---|---|
| **National Children's** | Our Lady's Children's Hospital, Crumlin | 5 |
| | Temple Street Children's University Hospital | 3 |
| **Ireland East** | Mater Misericordiae University Hospital Dublin | 11 |
| | St Vincent's University Hospital | 9 |
| | Royal Victoria Eye & Ear Hospital | 2 |
| | Cappagh National Orthopaedic Hospital | 1 |
| **Saolta** | Galway University Hospital | 27 |
| | Portiuncula University Hospital | 1 |
| **Dublin Midlands** | St James's Hospital | 21 |
| | Tallaght University Hospital | 7 |
| | Coombe Women & Infants University Hospital | 6 |
| | St Luke's Hospital, Rathgar | 1 |
| **South/ South West** | Cork University Hospital | 24 |
| | Mercy University Hospital, Cork | 2 |
| **RCSI** | Beaumont Hospital | 25 |
| | Connolly Hospital | 11 |
| | Rotunda Hospital | 6 |
| **UL** | University Hospital Limerick | 7 |

The number of CFAAs was subsequently compared to the total number of consultant posts in those hospitals where joint posts exist (i.e. Hospitals in Table 3, excluding hospitals where no dual appointments exists), and it was noted that **clinicians with a formal academic appointment represent a very small proportion (7%) of the total number of consultant posts in the hospitals.**

### 3.2.2. Distribution of Consultants with a Formal Academic Appointment by Discipline

The distribution of CFAAs was analysed by primary discipline and as a proportion of national distribution (see Table 4). **The majority were general surgeons (13%), followed by those in psychiatry (11%) and obstetrics and gynaecology (10%). The top three disciplines were disproportionately represented by CFAAs compared with the national picture. The remaining 27 specialities were each represented by fewer than 10% of clinicians.**

Table 4: Distribution of CFAA by discipline

| Discipline | CFAA | % of total CFAA | National % by discipline |
|---|---|---|---|
| General Surgeon | 25 | 13% | 6% |
| Psychiatry | 20 | 11% | 9% |
| Obstetrics and Gynaecology | 18 | 10% | 5% |
| Paediatrics | 13 | 7% | 4% |
| General Physician | 11 | 6% | 0% |
| Histopathology | 11 | 6% | 4% |
| Endocrinology and Diabetes Mellitus | 10 | 5% | 2% |
| Geriatrics | 7 | 4% | 4% |
| Microbiology | 7 | 4% | 2% |
| Anaesthesia | 7 | 4% | 13% |
| Respiratory | 7 | 4% | 2% |
| Gastroenterology | 6 | 3% | 2% |
| Infectious Diseases | 5 | 3% | 1% |
| Radiology | 5 | 3% | 9% |
| Haematology | 4 | 2% | 2% |
| Oral & Maxillofacial | 4 | 2% | 0.4% |
| Pharmacology & Therapeutics | 4 | 2% | 0.2% |
| Nephrology | 4 | 2% | 1% |
| Cardiology | 3 | 2% | 2% |

| Discipline | CFAA | % of total CFAA | National % by discipline |
|---|---|---|---|
| Otolaryngologist | 3 | 2% | 2% |
| Rheumatology | 3 | 2% | 1% |
| Ophthalmology | 3 | 2% | 1% |
| Emergency | 2 | 1% | 3% |
| Neonatology | 2 | 1% | 1% |
| Orthopaedic | 1 | 1% | 4% |
| Urology | 1 | 1% | 2% |
| Immunity | 1 | 1% | 0.3% |
| Genetics | 1 | 1% | 0.1% |
| Neurology | 1 | 1% | 2% |
| Radiation Oncologist | 1 | 1% | 1% |

# Survey Responses

**1,904**
valid survey responses. Majority of respondents were hospital based (40%).

Doctors 15%
Nursing 21%
HSCPs 32%

1 - 10 hours conducting research per week.

The majority of independent researchers were doctors.

**7%** of medical consultants have a joint university academic appointment.

Doctors & HSCPs have the highest proportion of PhDs (23% & 22%).

# 4. Activity Indicator 2: Research Studies

The following section explores the types and volume of research studies that the research active staff referred to above are engaged in. Data were received from a variety of sources including Research Ethics Committees, the Health Research Board, the EU participant portal, the EU clinical trials database, the HPRA and the research offices of third level institutions:

## 4.1 Studies Approved by Research Ethics Committees in 2017[15]

Research involving patients, either directly or indirectly (e.g. concerning their biological samples or their data), requires ethical approval. Much of the research taking place in the health service, therefore, requires Research Ethics Committee (REC) approval. In the absence of formal research project registers in most hospitals, community healthcare organisations and other parts of the health service, the RECs represent a unique repository of information about research activity.

Some RECs review proposals for both hospital and CHO based research, while others (mainly in the Dublin and surrounding region) review exclusively hospital-based research. There is a misalignment between the regional REC catchment areas (which are based on the old health board regions), and the Hospital Groups and CHOs, so analysis by Hospital Group or CHO area was not possible with the data received. With the exception of studies on general practice (which are approved nationally by the Irish College of General Practitioners REC), a regional approach to the analysis was deemed the most adequate given the nature of the datasets. Figure 16 indicates the regional division used for the analysis. Table 5 indicates the RECs associated with each region and the dataset time-period in question. Table 6 indicates the counties, hospitals and CHO sections covered by each REC region.

A total of 32 committees serving the health service nationally were identified. These include hospital and HSE regional RECs in addition to RECs in section 38/39 organisations. All 32 RECs were contacted to request information related to the project titles of research studies approved by the committees during 2017. The vast majority of committees responded with information (n = 30, 94%), although three reported information from 2016 (or earlier) rather than 2017 (Table 5). Beaumont Hospital and Daughters of Charity RECs did not submit title information (Table 5 and Table 6), therefore the East Region dataset is slightly incomplete. The time period of the datasets used for the analysis is indicated in Table 5.

Note that eleven (out of a total of 12) of the RECs that shared their information are approved by the Department of Health to review Clinical Trials of Investigational Medicinal Products (CT-IMP) at national level. As the origin of these studies could not be identified by the title alone, the analysis indicates regionalisation of REC approval rather than regionalisation of the actual research activity. Furthermore, non CT-IMP studies that involve multiple sites require multiple REC approvals, therefore the numbers include an undetermined level of duplication and hence indicate approvals rather than absolute project numbers.

15 See caveats in text related to dates of some datasets

Figure 16: REC regions used for the analysis

Table 5: RECs approached for information per region and time period of dataset supplied

| Region | Associated RECs | Year of data included in Analysis[16] | Total number of approvals per region |
|---|---|---|---|
| **Midlands Region** | HSE Midlands Area REC[17] | 2017 | 32 |
| **Mid-Western Region** | #HSE Mid-Western Area & University of Limerick Hospital Group REC[17] | 2017 | 157 |
| **South East Region** | #HSE South-Eastern Area REC[17] | 2017 | 72 |
| **North East Region** | #HSE North East Area REC[17] | 2017 | 21 |
| **South/South West Region** | #Clinical REC of the Cork Teaching Hospitals (CREC) at UCC[18] | 2017 | 526 |
| **West/North West Region** | Sligo University Hospital REC[19] | 2017 (n = 43) | 367 |
| | Mayo University Hospital REC[20] | 2017 (n = 31) | |
| | Letterkenny University Hospital REC[20] | 2017 (n = 17) | |
| | #Galway University Hospital REC[19] | June '16 – Feb '17 (n = 276) | |
| **East Region** | Cappagh National Orthopaedic Hospital REC[21] | 2017 (n = 9) | 597 |
| | Connolly Hospital REC[21] | 2017 (n = 14) | |
| | Coombe Hospital REC[21] | 2017 (n = 30) | |
| | Enable Ireland[21] | 2016 (n = 2) | |
| | #Mater Misericordiae REC[21] | 2017 (n = 34) | |
| | Naas General Hospital[21] | 2017 (n = 9) | |
| | #National Maternity Hospital REC[21] | 2017 (n = 36) | |
| | National Rehabilitation Hospital REC[21] | 2013 (n = 4) | |
| | #Our Lady's Children's Hospital, Crumlin REC[21] | 2017 (n = 83) | |
| | Rotunda Hospital REC[21] | 2017 (n = 13) | |
| | Royal Victoria Eye & Ear Hospital REC[21] | 2017 (n = 11) | |
| | St John of God[21] | 2017 (n = 24) | |
| | St Luke's Hospital, Rathgar REC[21] | 2017 (n = 5) | |
| | St Michael's House[21] | 2017 (n = 14) | |
| | #St. Vincent's Hospital REC[21] | 2017 (n = 93) | |
| | Stewarts Hospital[21] | 2017 (n = 1) | |
| | Temple Street Children's Hospital REC[21] | 2017 (n = 78) | |
| | TUH/ SJH Joint REC[21] | 2017 (n = 135) | |
| | Laura Lynn[21] | 2017 (n = 2) | |
| | ^#Beaumont Hospital REC[21] | 2017 (n=78) | |
| | *Daughters of Charity[21] | *No data supplied. #National REC for approval of IMP clinical trials. | |
| **National** | #Irish College of General Practitioners REC | 2017 | 57 |
| **TOTAL number of REC reviews** **(Note: some proposals are reviewed by more than one REC, hence the total number of projects is, therefore, less than the total number of reviews)** | | | **1,829** |

^ Submitted total number of studies but no further data, hence these projects are not included in further analysis.
* No data supplied.
\# National REC for approval of IMP clinical trials.

16 Some RECs submitted data in different year period due to administrative capacity constraints.
17 Regional Research Ethics Committees: Reviews Hospital and CHO based research.
18 University based REC which reviews Hospitals and CHO based research.
19 Hospital based RECs which also review CHO based research.
20 Hospital based REC which reviews Hospital based research only (some review community research occasionally.
21 Community Services (Section 39) Organisation REC.

Table 6: REC regional coverage (counties, hospitals, CHO or CHO section)

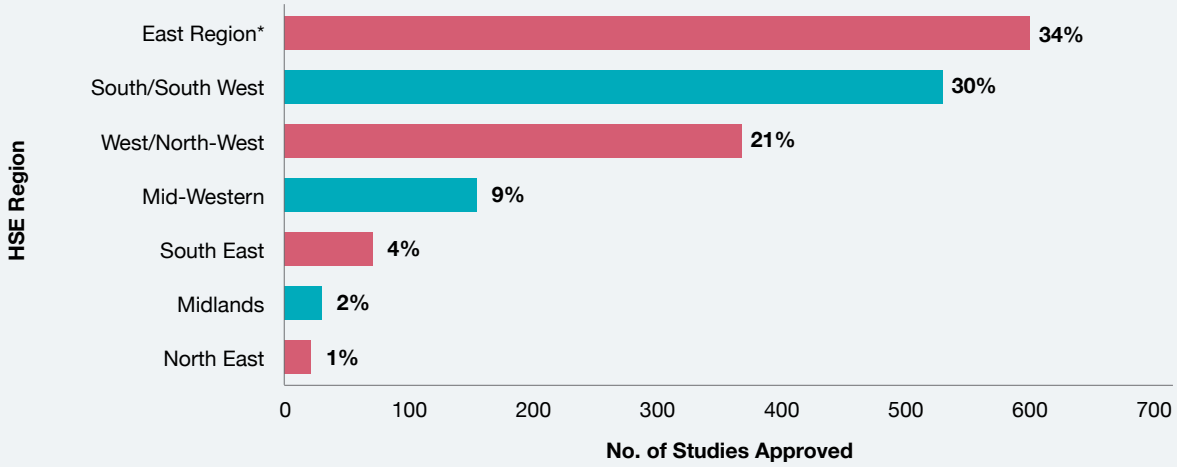
| RECs | Counties | Hospitals | CHO |
|---|---|---|---|
| HSE Midlands REC | Longford, Westmeath, Offaly, Laois. | **Ireland East HG Hospitals:**<br>• Midland Regional Hospital Mullingar<br>**Dublin Midlands HG Hospitals:**<br>• Midland Regional Hospital Portlaoise<br>• Midland Regional Hospital Tullamore<br>• Naas General Hospital | CHO8 (Laois, Offaly, Westmeath) |
| HSE Mid-Western Area REC | Limerick, Clare, North Tipperary. | **University Limerick HG Hospitals:**<br>• Mid-Western Regional Hospital<br>• Limerick Ennis General Hospital<br>• Nenagh General Hospital<br>• St John's Hospital<br>• Limerick Mid-Western Regional Maternity Hospital<br>• Mid-Western Regional Orthopaedic | CHO3 |
| HSE South-Eastern Area REC | Kilkenny, Wexford, Carlow, Waterford, South Tipperary. | **Ireland East HG Hospitals:**<br>• St Luke's General Hospital Carlow Kilkenny<br>• Wexford General Hospital<br>**South/ South West HG Hospitals**<br>• University Hospital Waterford<br>• South Tipperary General Hospital<br>• Lourdes Orthopaedic Hospital, Kilcreene | CHO5 |
| HSE North East Area REC | Monahan, Cavan, Louth, Meath | **Ireland East HG Hospitals:**<br>• Our Lady's Hospital, Navan<br>**RCSI HG Hospitals:**<br>• Cavan and Monaghan Hospital<br>• Our Lady of Lourdes Hospital, Drogheda<br>• Louth County Hospital Dundalk | CHO1 (Cavan and Monahan)<br>CHO 8 (Louth and Meath) |
| Clinical REC of the Cork Teaching Hospitals (CREC) at UCC | Cork, Kerry | **South/South West HG hospitals:**<br>• Cork University Hospital/ Cork University Maternity Hospital<br>• University Hospital Kerry<br>• Mercy University Hospital<br>• South Infirmary Victoria University Hospital<br>• Bantry General Hospital<br>• Mallow General Hospital | CHO 4 |

| RECs | Counties | Hospitals | CHO |
|---|---|---|---|
| SUH REC<br>MUH REC<br>LUH REC<br>GUH REC | Galway, Sligo, Mayo, Roscommon, Leitrim, Donegal | **Saolta Hospital Group:**<br>• Galway University Hospital<br>• Sligo University Hospital<br>• Letterkenny University Hospital<br>• Mayo University Hospital<br>• Merlin Park University Hospital<br>• Portiuncula University Hospital | CHO 1 (Donegal, Sligo, Leitrim)<br>CHO 2 (Mayo, Roscommon, Galway) |
| Rotunda Hospital REC<br>St Luke's Hospital REC<br>RVEEH REC<br>NRH REC<br>Temple St. Children's Hospital REC<br>NMH REC<br>Mater Misericordiae REC<br>TUH/ SJH Joint REC<br>CNOH REC<br>Stewarts Hospital<br>St Michaels House<br>Enable Ireland<br>Connolly Hospital REC<br>Coombe Hospital REC<br>Beaumont Hosp. REC<br>OLCHC REC<br>SVUH REC<br>Naas General Hospital REC<br>St John of God REC<br>Laura Lynn REC<br>Daughters of Charity REC | Dublin, Wicklow & Kildare | **RCSI HG Hospitals:**<br>• Rotunda Hospital Dublin<br>• Connolly Hospital Dublin<br>• Beaumont Hospital<br>**Ireland East HG Hospitals:**<br>• Mater Misericordiae University Hospital Dublin<br>• St Michael's Hospital, Dun Laoghaire<br>• Cappagh National Orthopaedic Hospital Dublin<br>• Royal Victoria Eye and Ear Hospital Dublin<br>• National Maternity Hospital Dublin<br>• St Vincent's University Hospital Dublin<br>• St Columcille's Hospital Loughlinstown<br>**Dublin Midlands HG hospitals:**<br>• St James' Hospital Dublin<br>• St Luke's Radiation Oncology Network<br>• Tallaght University Hospital<br>• The Coombe Women & Infants University Hospital<br>• Naas General Hospital<br>**Children's Hospital Group:**<br>• Our Lady's Children's Hospital, Crumlin<br>• Temple Street Children's University Hospital | CHO 6<br>CHO 7<br>CHO 9 |

### 4.1.1. Research Categories and Geographical Distribution

The titles of 1,772 research proposals reviewed by the RECs in each region (projects reviewed by ICGP REC not included here as it has national remit, see section 4.1.2) were categorised according to the UK Health Research Classification system (UK HRCS) as per the Methodology section. This dataset represents total studies reviewed by these RECs in 2017 (with some exceptions, see Table 5). The East region, which has 20 out of the 32 RECs, approved 34% of the total number of studies followed by the South/South West region (1 REC) and the West/North West region (4 RECs) (Figure 17).

Figure 17: Number of proposals approved per region in 2017 or nearest year as indicated in Table 5




*The data for East region is slightly incomplete as indicated in Table 5 and Table 6

**Generic Health Relevance** accounted for **almost a quarter** of all studies approved (Figure 18). This refers to research applicable to all diseases and conditions or to the general health and wellbeing of individuals, public health research, epidemiology and health services research that is not focused on specific conditions or underpinning biological, psychosocial, economic or methodological elements specific to individual diseases.

**Cancer, Mental Health, Reproductive Health and Childbirth, Cardiovascular and Neurological** were the next most prevalent research activity categories (Figure 18). Analysis by region shows a similar emphasis on Generic Health Relevance although the South East showed higher rates of **Mental Health** research, closely followed **by Midlands and North East** regions (Figure 19, and Appendix 2).

Figure 18: Percentage and numbers of REC approved studies for the six top health categories nationally

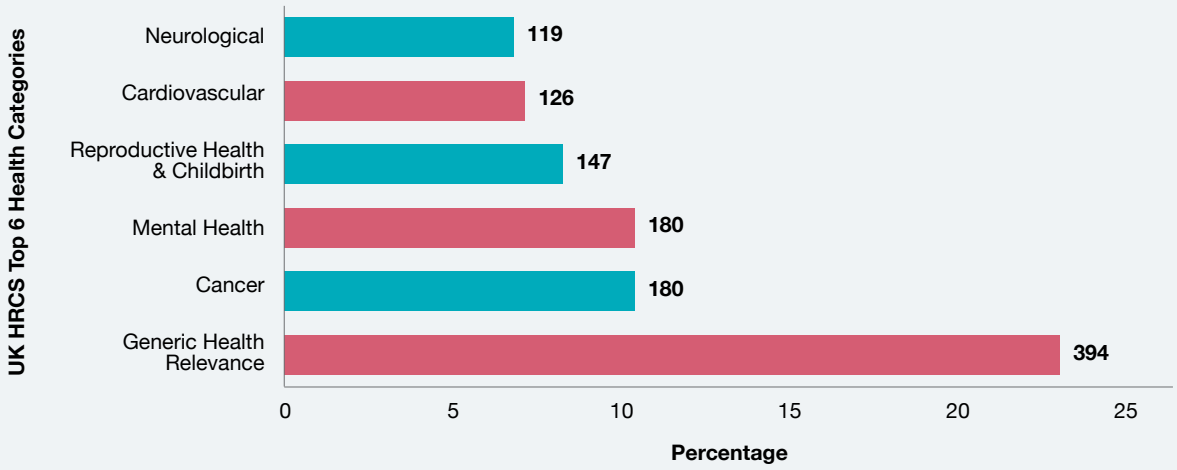
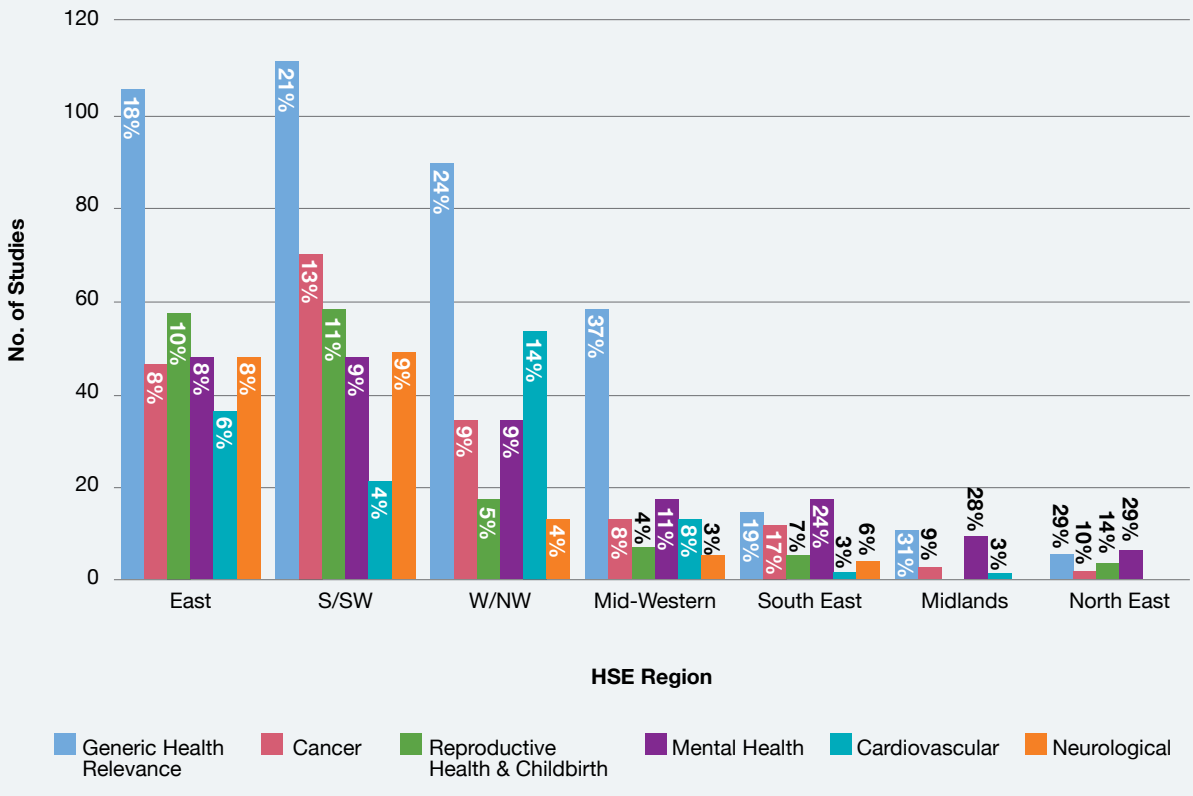


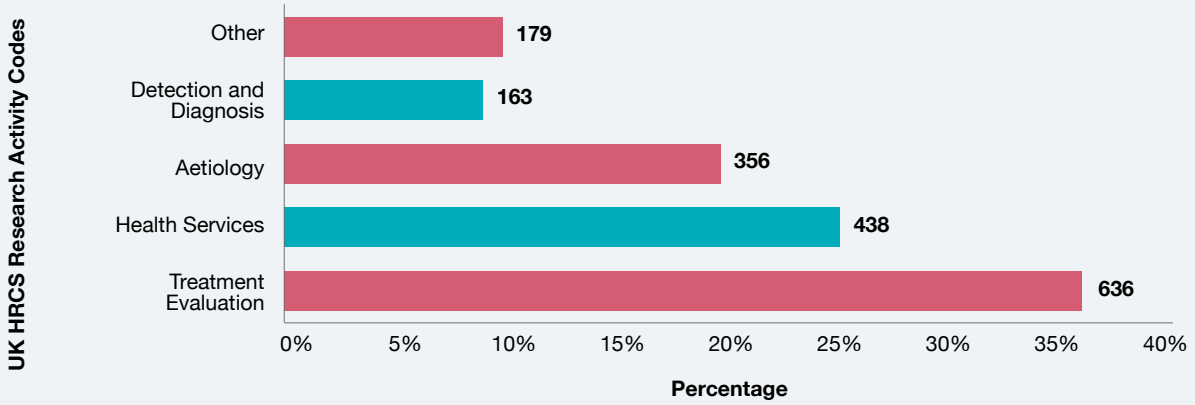

Figure 19: Percentage and number of REC approved studies for the six top health categories per region Percentage and numbers




*Data for East region is slightly incomplete as indicated in Table 5 and Table 6

Further analysis by research activity type, indicated that **Treatment Evaluation was the most frequent type of research activity (36%). This was closely followed by studies related to Health Services Research (25%) and Aetiology (20%)** (Figure 20).

Figure 20: Percentage and number of studies classified by research activity in the overall sample




Research activity analysis by region indicates that national distribution is aligned with regional distribution in the **South/South-West, West/North-West and East, with treatment evaluation, health services research and aetiology accounting for the largest proportion** of research activity (Figure 21). **In the remaining regions** (Figure 22), **health services research accounts for the majority of approved studies,** i.e. Mid-Western (50%), South-East (37%), Midlands (31%) and North-East (38%).

Figure 21: Percentage and number of studies classified by type of research activity for the regions with more annual project throughput

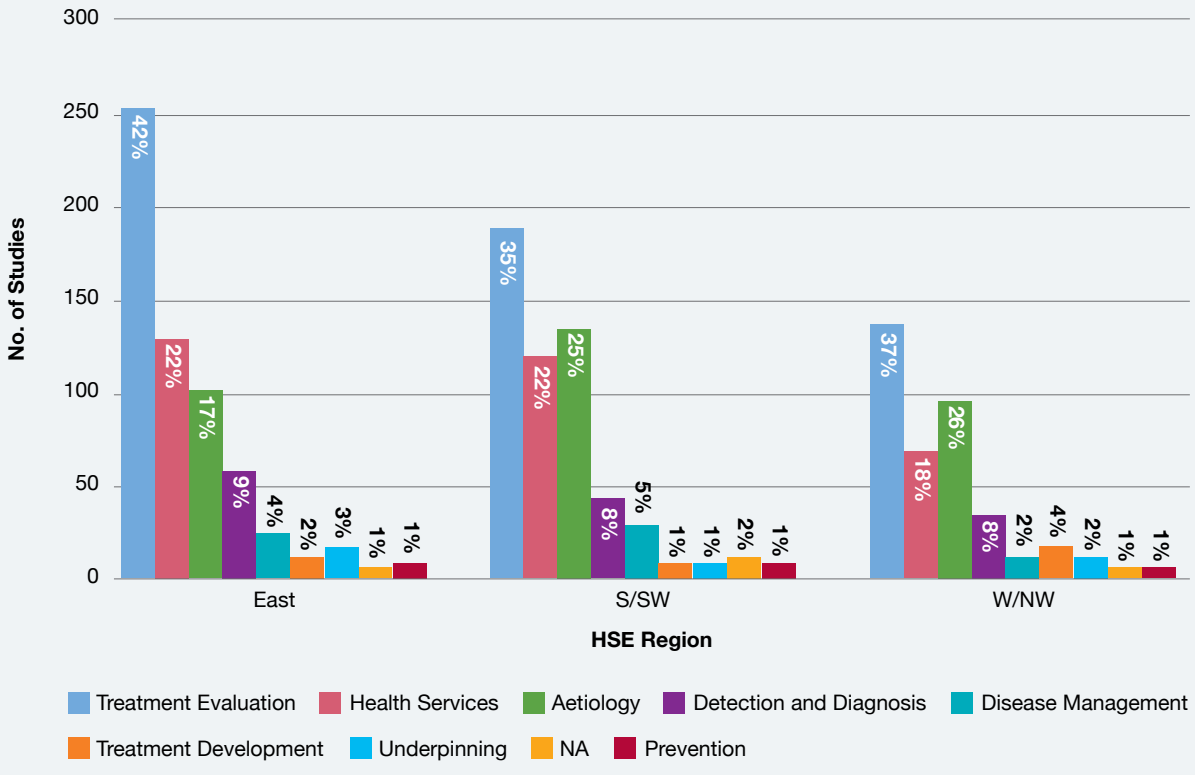
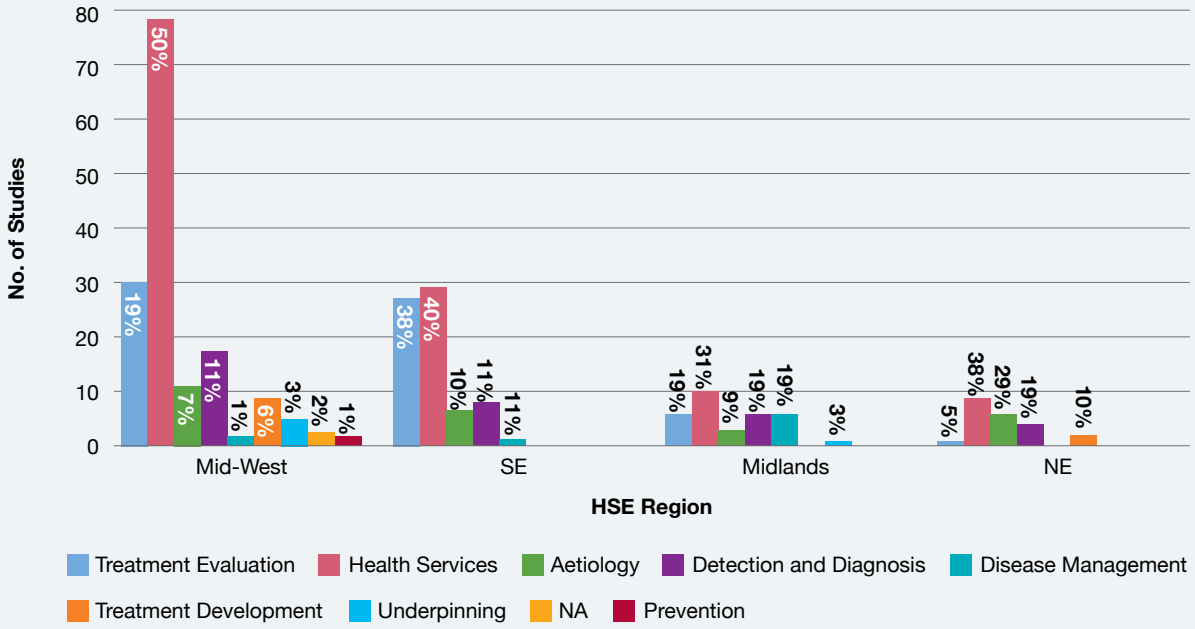


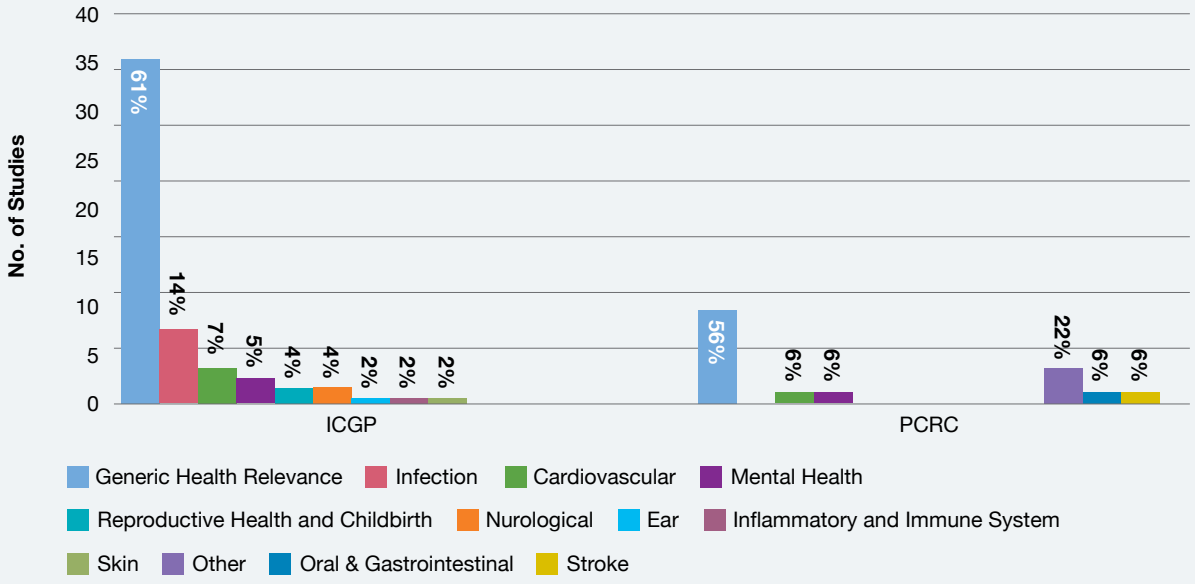
Figure 22: Percentage and number of studies classified by type of research activity for the regions with less annual project throughput




## 4.1.2. Research in Primary Care and General Practice

National data were also received for research studies in primary care from the Primary Care Research Committee* (PCRC, n = 18 studies in 2017), and for research studies in general practice from the Irish College of General Practitioners (ICGP) REC (n = 57 studies in 2017). The **vast majority of studies were of Generic Health Relevance** with 61% and 56% for ICGP and PCRC respectively (Figure 23).

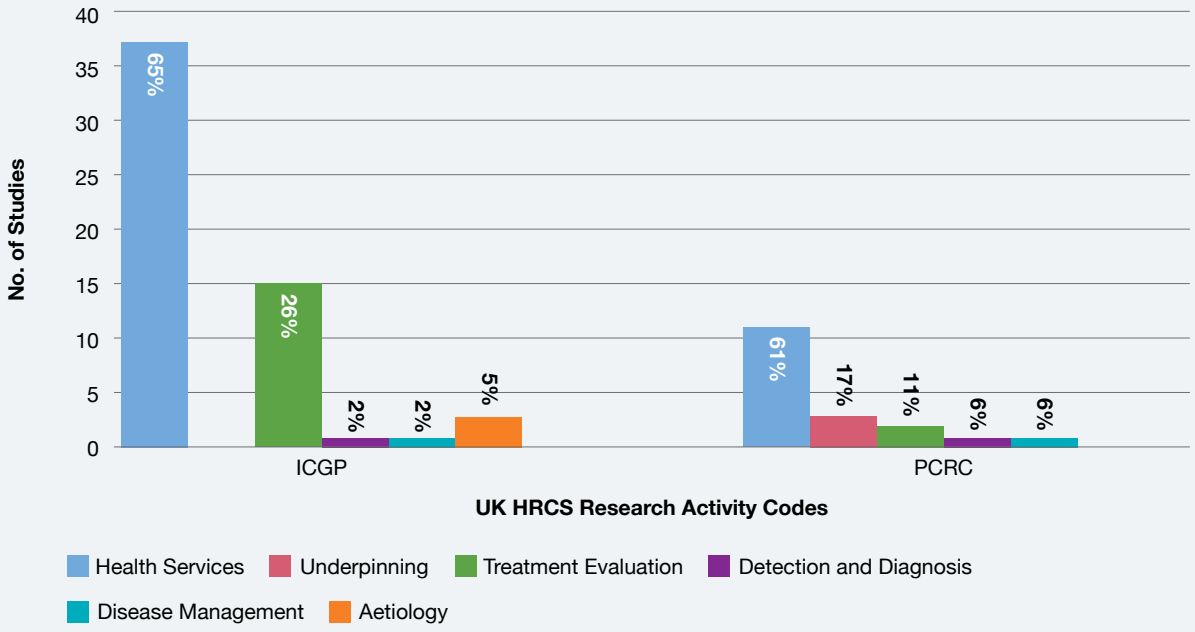
Figure 23: Percentage and number of studies by health categories from the ICGP and PCRC at national level




* Note that the PCRC is not a REC, but a governance body that approves research projects for Primary Care in the CHOs which have prior REC approval. Hence the studies in the PCRC sample (n=18) are also included in the analysis of section 4.1.1.

Analysis by research activity indicated that the majority of research activity related to health services research, accounting for 65% of approved studies by ICGP and 61% by the PCRC (Figure 24).

Figure 24: Percentage and number of studies by research activity from the ICGP and PCRC at national level




## 4.2 HRB funded Studies with Healthcare Professionals as PIs or Co-PI in 2017

The Health Research Board (HRB) is a state agency and the funding arm of the Department of Health. The HRB funds health research to provide evidence to prevent illness, to improve health and to contribute towards the transformation of patient care. The HRB has an annual budget of over €45 million, and manage a research investment portfolio of approximately €200 million on an annual basis. To be eligible for funding, a recipient must be affiliated with a pre-approved organisation that has been awarded 'research host institution' status, with the capacity to robustly manage the associated financial reporting requirements, and the management of intellectual property. **Hospitals and HSE funded healthcare delivery organisations do not hold the status of "research host organisation" and therefore cannot receive direct funding from the HRB. Hence funding received from the HRB for studies involving healthcare staff is generally awarded to the university sector.**

The HRB kindly provided information about studies awarded over the last five years. In order to maintain a consistent approach across the different project-related datasets, only 2017 data are presented for the purpose of this report. The dataset was generated through the HRB grants application system (Grant E-Management System known as GEMS). It identified individuals listed as grant recipient Principal Investigators (PIs), Co-PIs or Co-Applicants who had indicated that they were a 'health professional'. Within GEMS, a health professional is anyone with a recognised qualification chosen from the following list (and includes those with a dual appointment with a third level institute):

- Dentistry
- Dietetics / Nutrition
- Medical / Surgical Doctor

- Nurse or Midwife
- Clinical Research Nurse
- Occupational Therapy
- Ophthalmology / Visual Sciences
- Pharmacy or Pharmacology
- Physiotherapy
- Podiatrist / Chiropodist
- Psychology or Behavioural Science
- Radiography
- Social Care or Social Services
- Speech and Language Therapy

The dataset includes all awards, which are mainly project type awards, but also includes funding for HRB funded Clinical Research Facilities.

### 4.2.1. HRB Studies Awarded to HCPs in 2017

During 2017 the HRB issued a total of 118 awards worth €79,690,355 (Figure 25 & Figure 26). Of the 118 awards, 38% involved healthcare professionals (HCP) (n = 45) in the capacity of PI, Co-PI or Co-Applicant (Figure 25), which represented 56% of the funding awarded (Figure 26).

Figure 25: Number of HRB awards issued in 2017 for Healthcare Staff and Non-Healthcare Staff

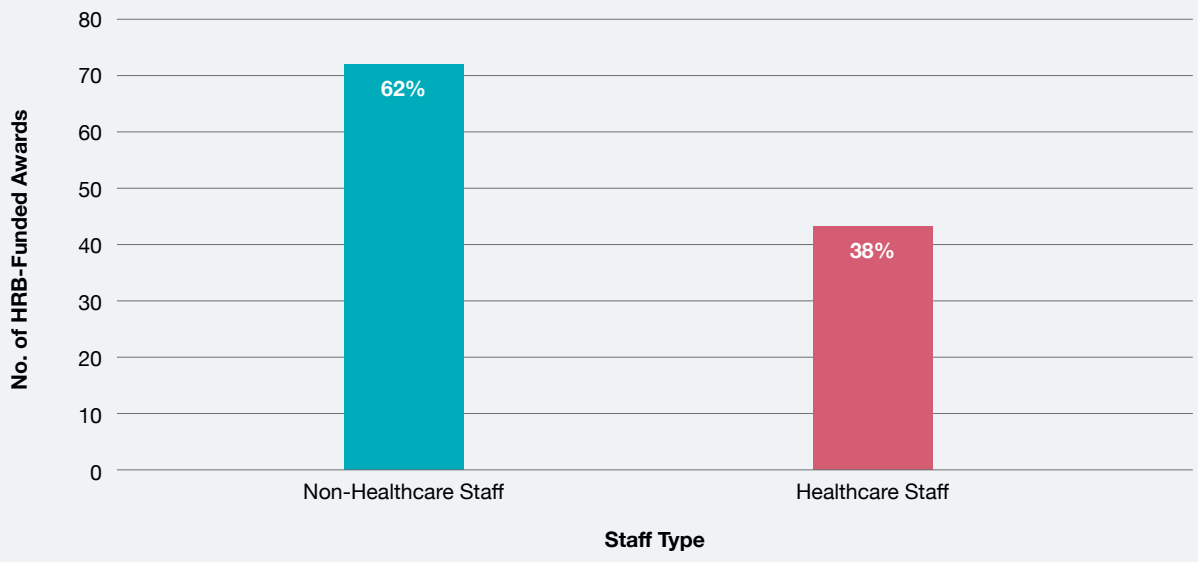
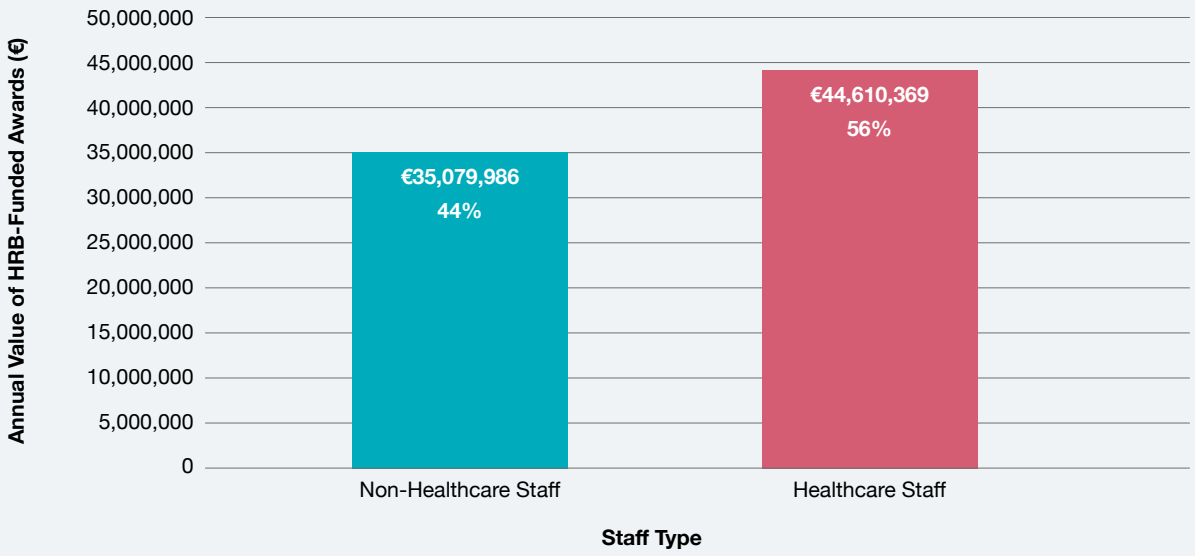
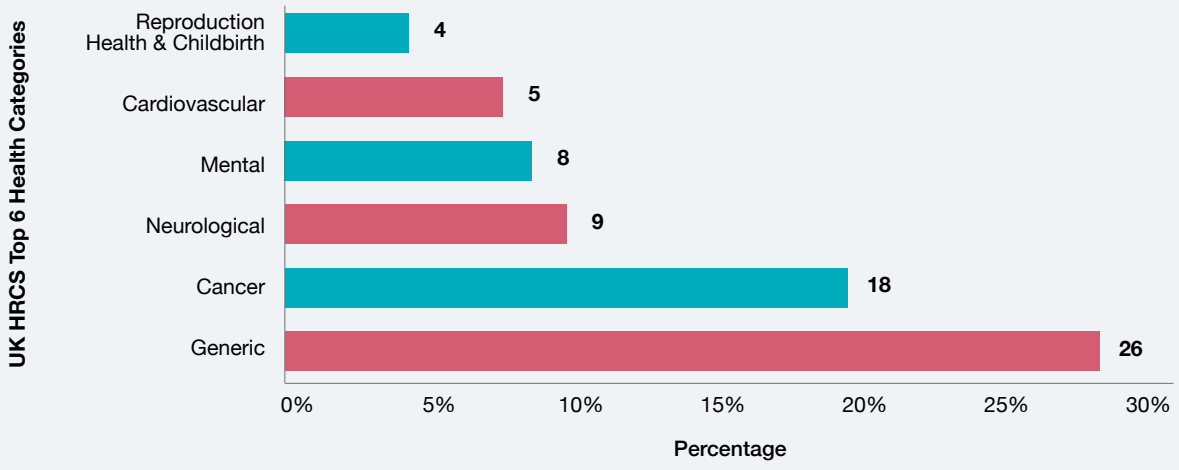


Figure 26: Annual value of HRB awards issued in 2017, for Healthcare Staff and Non-Healthcare Staff




Analysis by HRCS Health Categories codes (Figure 27) showed that the top funded focus areas were Generic Health Relevance (28%), Cancer (19%), Neurological (10%), and Mental health (9%).

Figure 27: Percentage and number of HRCS top 6 health categories for HRB funded research studies in 2017



### 4.2.2. HRB studies awarded to CFAAs in 2017

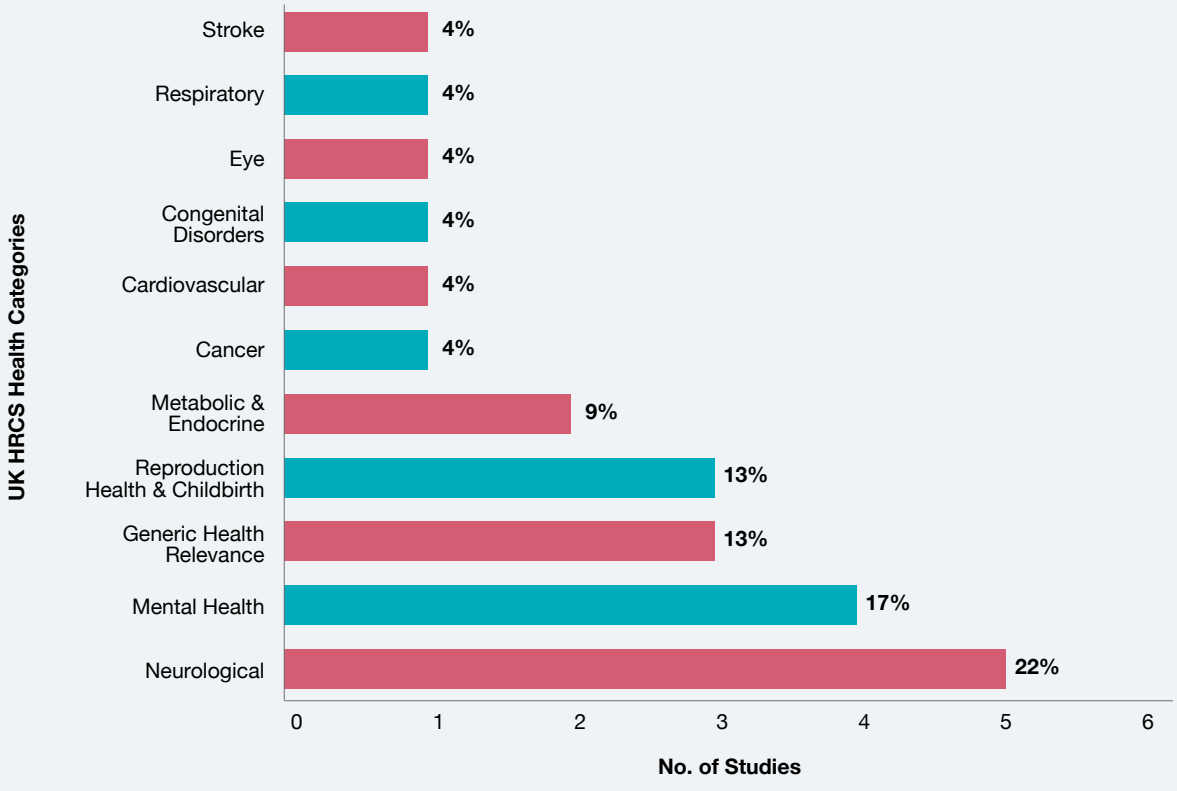
The number of HRB awards made to medical consultants with a formal academic appointment (CFAA) was subsequently analysed. **From the 45 HRB grants involving HCPs in 2017; 23 grants were awarded to 18 CFAAs** (five of them received two awards).

As indicated in Section 3.2, there were a total of 189 CFAAs in 2018. If we assume no major changes in the number of these positions between 2017 and 2018, this indicates **that only 9.5% of CFAAs are in receipt of HRB funding. The total amount of funding received by this cohort amounted to €23,093,127; which represents 29% of all HRB grants, and 52% of all HRB grants awarded to healthcare staff.**

The health categories of these studies awarded to this cohort were further analysed. **Generic Health Relevance and Mental Health** (Figure 28) **were the top categories.** This is consistent with the fact that Psychiatry is one of the top disciplines for CFAAs (Section 3.2.2, Table 4).

Analysis by research activity area indicated that **the majority of studies related to Aetiology (22%), Treatment Evaluation (17%) and Prevention (17%).**

Figure 28: Percentage and number of HRB-funded studies by health categories by CFAAs



## 4.3. EU Funded Studies involving the HSE in 2017

The main research funding vehicle of the European Commission is the Horizon 2020 programme. This programme (2014 to 2020) is the largest EU research and innovation programme to date, with funding of almost €80 billion being made available. The programme is based around partnerships with other European institutional collaborators and industry. Horizon 2020 funds health research under many of their different programmes, in particular, the calls under Societal Challenges.

The EC also funds health research via the Third Health Programme, which is the main instrument that the Commission uses to implement the EU Health Strategy. It targets initiatives to promote health, to prevent diseases, and to facilitate access to better and safer healthcare, among others.

Information related to EU funded studies involving the HSE was obtained from the EU participant portal. **In 2017 there were six EU funded studies in which the HSE was a project partner. These included three Horizon 2020 awards and three from the Third Health Programme.** The HSE participated as a partner rather than as the coordinator in all studies.

EU funded studies usually involve participants from several EU countries, with the number of partners per study in this dataset ranging from 13 to 109. **The total award value of these studies (for all partners) in 2017 was €102,317,219. Of this, €695,245 was awarded to the HSE in 2017.** The total value of EU research funding received by the HSE in the last 10 years (from 2009 to 2019) is € 2,019,069.56.

Classification using the UK Health Research classification system showed that **the majority of studies were of Generic Health Relevance (n = 4, 67%), and the remainder related to Environmental Health (n = 2, 33%).**

## 4.4. Regulated Clinical Trials (medicinal products) and Clinical Investigations (medical devices)

Health Products Regulatory Authority (HPRA) regulated clinical research falls into two categories: clinical trials of investigational medicinal products (CT-IMP) and clinical investigations of medical devices.[22] In Ireland, the HPRA is designated as the Competent Authority for their regulation and ensures compliance with the EU legislation [European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations, 2004, transposed into Irish law through SI No 190 of 2004].[23]

For the purpose of this report, the term **Clinical Trial** is used as defined in the legislation (SI No 190 of 2004); any investigation in human subjects, other than a non-interventional trial, intended to:

a) Discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more investigational medicinal products, or

b) Identify any adverse reactions to one or more such investigational medicinal products, or

22 https://www.hpra.ie/

23 S.I. No. 190/2004 - European Communities (Clinical Trials on Medicinal Products For Human Use) Regulations, 2004. Available on http://www.irishstatutebook.ie/eli/2004/si/190/made/en/print. Accessed on December 06, 2018.

c) Study absorption, distribution, metabolism and excretion of one or more such investigational medicinal products, or

d) Discover, verify, identify or study any combination of the matters referred to at subparagraphs (a), (b), and (c), with the object of ascertaining the safety or efficacy of such products, or both.

Regulated clinical trials are also subject to the guidance of ICH GCP (International Conference on Harmonisation-Good Clinical Practice) and the Declaration of Helsinki. In addition to HPRA approval, clinical trials must also be approved by a designated Research Ethics Committee (REC). There are currently 12 Research Ethics Committees (REC) in Ireland recognised and authorised by the Department of Health to consider an application for IMP clinical trials.[24]

The other main type of regulated study is a **Clinical Investigation of a Medical Device**. These are also regulated by EU law which was enacted in April 2017.[25] These are regulated by the HPRA and the National Standards Authority of Ireland (NSAI) Regulations, and also require ethical approval. The medical devices regulation overlaps in many areas with the clinical trials regulations, but unlike those, there is no provision for a single national ethics opinion for multi-site regulated Clinical Investigations.

Regulated studies require a sponsor, which is a person or entity that takes responsibility for the initiation, management and/or financing of the study. The sponsor does not need to be located in an EU Member State but must have a legal representative in the EEA. The investigator and the sponsor may be the same person, and the sponsor may delegate any or all of his trial-related duties and functions to another person or organisation. The sponsor remains responsible for ensuring that the conduct of the trial and the data generated comply with all relevant regulations.

### 4.4.1. Regulated Clinical Trials in Ireland in 2017

Information about Irish Regulated Clinical Trials is available in the EU Clinical Trials Register (EudraCT). This register contains information on authorised interventional clinical trials of medicines conducted in the European Union (EU), or the European Economic Area (EEA), after May 01, 2004. The Register contains Phase II-IV clinical trials on adults and paediatric populations conducted in the EU / EEA, and registration on this register is compulsory for all such regulated trials.

Studies are registered by the study sponsor, and the database is used by the HPRA for data related to clinical trial protocols. The HPRA adds the authorisation only when a favourable ethics committee opinion is provided by the sponsor. **While the sponsors are, in many cases, pharmaceutical companies, organisations such as Cancer Trials Ireland (CTI), HRB Clinical Research Coordinator Ireland (HRB-CRCI) have a key role in coordinating and supporting these trials. In addition, some universities can also take the role of sponsor.**

24 Research Ethics Committees in Ireland recognised to consider applications for clinical trials. Department of Health 2012.

25 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

For the purpose of this study, the EU clinical trials database was searched for clinical trials that were conducted in Ireland in 2017 (those which had been authorised by the HPRA and for which the HPRA have received confirmation of REC approval).

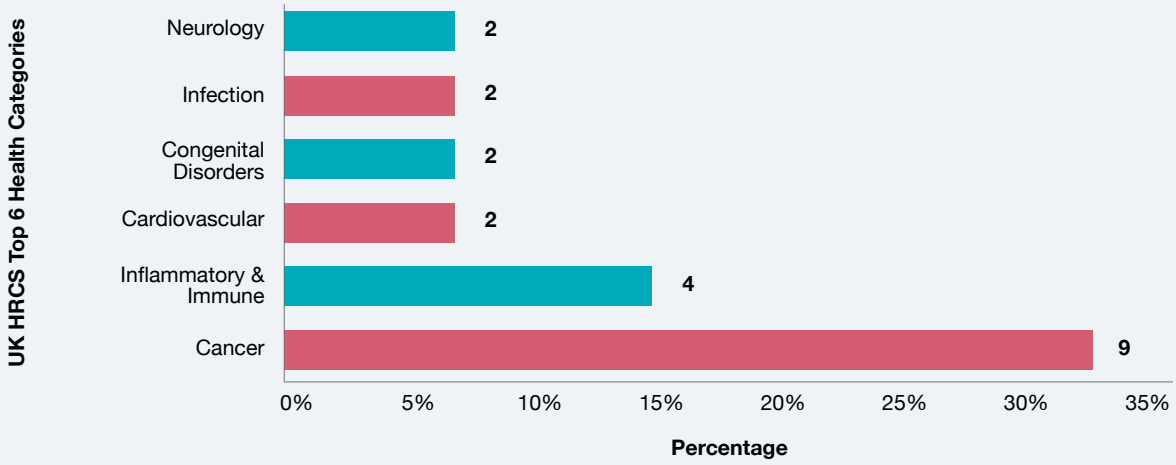
According to the information in EudraCT, **27 clinical trials with an Irish site location were recorded as having a start date (the date the study was authorised to proceed) in 2017. There were an additional 70 clinical trials identified as 'on-going' with an Irish site location.** All 97 clinical trials have been approved by the HPRA. **These figures are significantly lower than countries with a similar population; Denmark and Finland, which had 365 and 180 clinical trials respectively registered on EudraCT during the same time period.**

**The majority of these Irish clinical trials were sponsored by industry** (n = 24, 89%). AbbVie Deutschland GmbH & Co. KG and Aimmune Therapeutics, Inc., were the most common sponsor, with three trials each. **The remaining three non-industry sponsored trials were sponsored by a foreign university, an Irish hospital and a HSE community area.**

According to the UK HRCS categories, **the majority (n = 9, 33%) of these clinical trials were related to Cancer and 15% (n = 4) were related to Inflammatory and Immune** diseases (Figure 29).

**Treatment Evaluation represented 92.6% (n = 25), while Disease Management (n = 1, 3.7%) and Treatment Development (n = 1, 3.7%) accounted for the remainder.**

Figure 29: Percentage and number of Irish clinical trials by the six most frequent HRCS health categories on the EudraCT

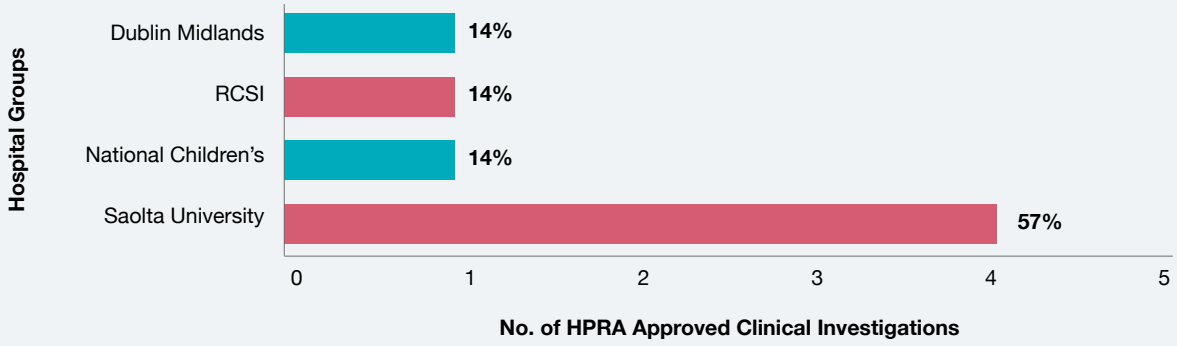


### 4.4.2. Clinical Investigation of Medical Devices

Information related to approved clinical investigations of medical devices during the same time period was provided by the HPRA. **In 2017 there were seven clinical investigations of medical devices approved by the HPRA.**

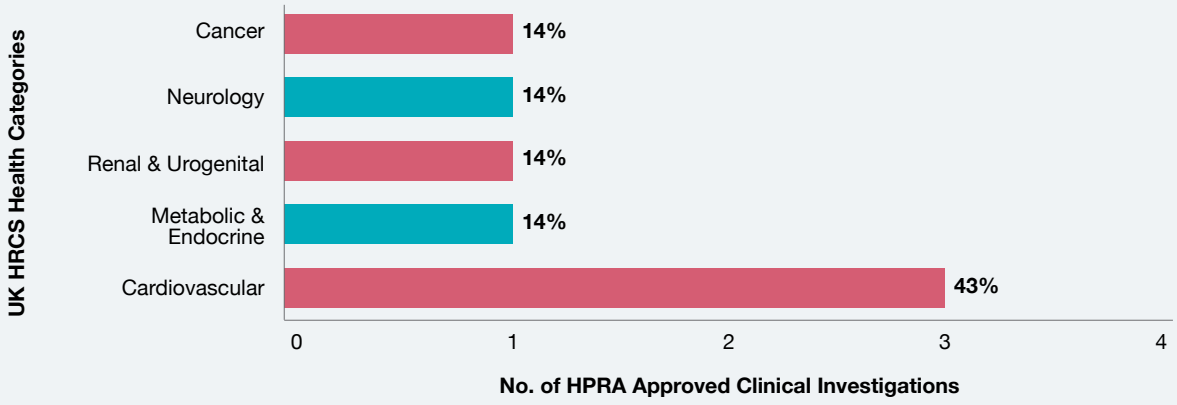
**The studies were sponsored by seven different entities, of which only one was an Irish academic sponsor, with the remaining five studies sponsored by industry.** Saolta University Health Care Group hosted the highest number of approved clinical investigations; n = 4, 57% (Figure 30).

Figure 30: Percentage and number of HPRA approved clinical investigations by Hospital Group




According to the UK HRCS categories, **the majority (n = 3, 43%) of these clinical investigations related to devices for Cardiovascular conditions** (Figure 31). **Treatment Evaluation represented 71% (n = 5), while Detection and Diagnosis accounted for the remainder.**

Figure 31: Percentage and number of HPRA approved clinical investigations by health categories



## 4.5. Research Related Activity in the Third Level Sector Funded by the HSE in 2017

The HSE engages the Irish university sector to commission health services research and to evaluate related studies. The research support offices in the Universities and Institutes of Technology kindly provided information about studies funded by the HSE over the last five years. For the purpose of this report, only 2017 data has been included to ensure consistency with the other datasets.

**In 2017 the HSE-funded 56 studies within 10 different HEIs (Table 7), which totalled almost €6.5 million.**

Table 7: Studies/collaborations by HEI

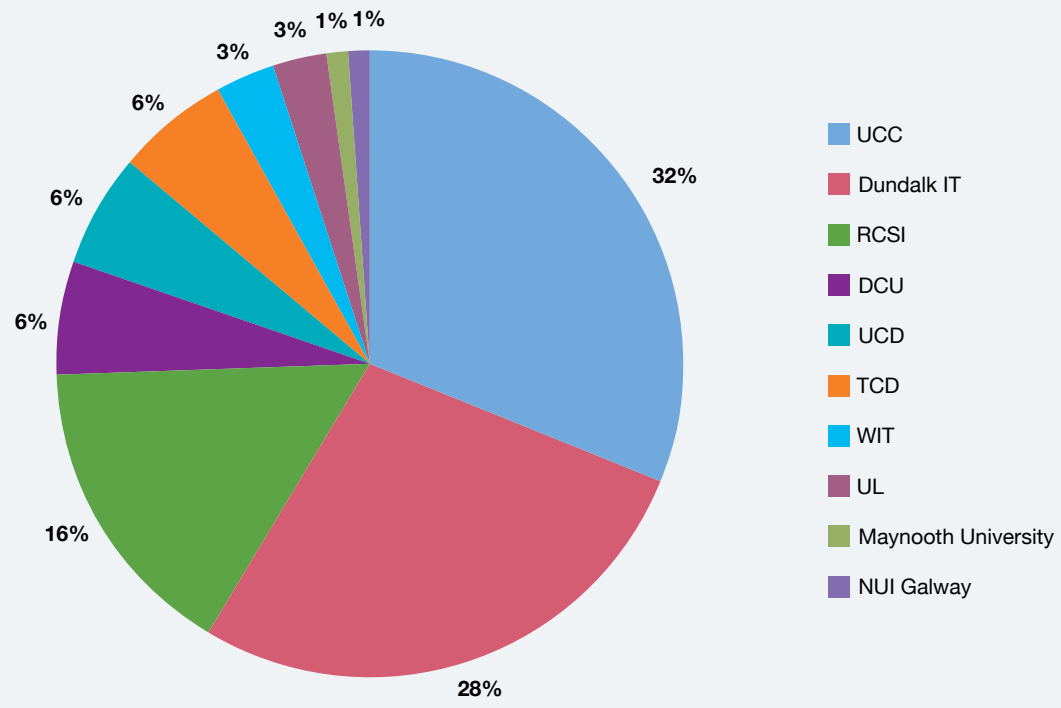
| Higher Education Institution | Number of Studies / Collaborations | Percentage of Total Studies / Collaborations |
|---|---|---|
| University College Cork | 17 | 30 |
| University College Dublin | 9 | 16 |
| Royal College of Surgeons in Ireland | 8 | 14 |
| Trinity College Dublin | 8 | 14 |
| Dublin City University | 5 | 9 |
| Waterford Institute of Technology | 3 | 5 |
| University of Limerick | 3 | 5 |
| NUI Galway | 1 | 2 |
| Dundalk Institute of Technology | 1 | 2 |
| Maynooth University/ NUI Maynooth | 1 | 2 |

**University College Cork secured the largest number of studies (30%)** (Table 7), **and the highest proportion of HSE funding over the period, representing 32% (€2,112,996) of the total spend** (Figure 32).

Dundalk IT received the second largest amount of funding from the HSE despite having just one project (€1,804,580, 28% of the total funding), followed by RCSI (€1,036,751, 16% of the total funding). The proportion of funding varies between 6% and 0.2% for the remaining seven HEIs.

The low number among some of the other institutions may be due to studies being conducted between a given HEI and voluntary hospitals (rather than a HSE institution). Also, it is not clear if studies recorded as "funded by HSE" in the HEIs information management systems referred to funding from HSE Corporate / National Departments or to HSE funded organisations (i.e. some universities may have recorded funding from a HSE hospital by the hospital name which will then exclude it from the search criteria).

Figure 32: Percentage proportion of funding by HEI in 2017




When categorised by health category, the majority of **HSE funded studies were of Generic Health Relevance; 68%** (Figure 33). This is not unexpected since universities would generally be contracted to conduct evaluative research, for example, based on changes in service delivery. With regard to research activity type, **Health Services research was the most prominent at 65%** (Figure 34).

Figure 33: Percentage and number of studies by top six HRCS health categories

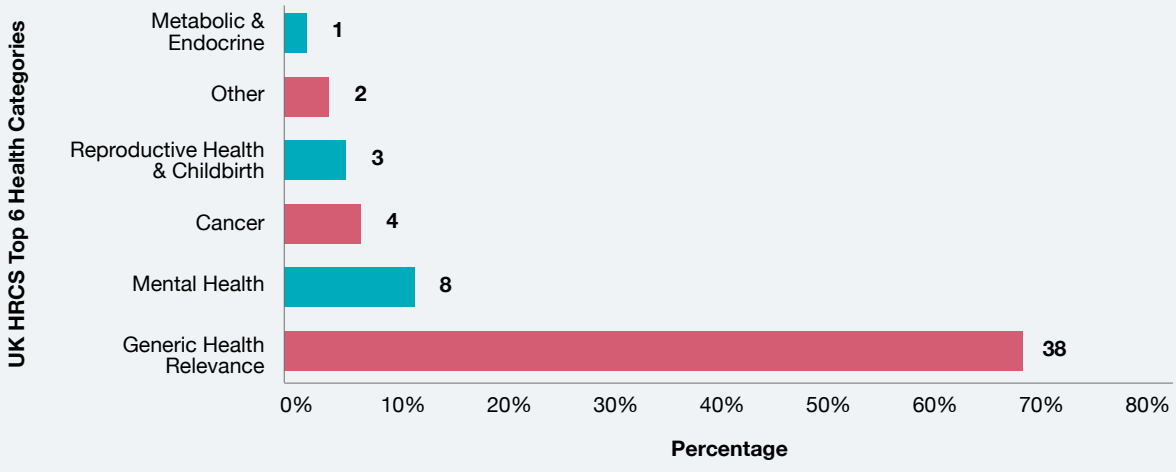
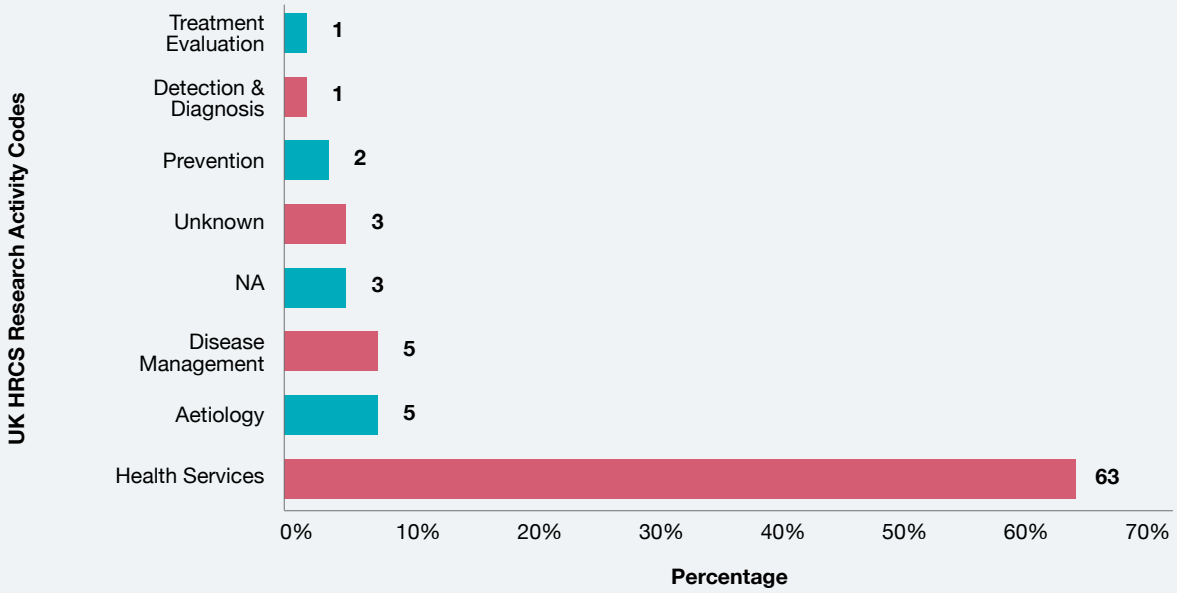


Figure 34: Percentage and number of studies by HRCS research activity codes



# Research Studies undertaken

The majority (1/4) of REC approved studies were of 'Generic Health Relevance'

**56** research projects commissioned by the HSE from third level institutions

51 Grant Awards
45 HRB
6 EU

34 HPRA Regulated studies
27 new clinical trials
7 new medical device trials

**32** Research Ethics Committees

1,829 REC approvals

# 5. Activity Indicator 3: Scopus Indexed Publications, 2013-2017

One important measure of research activity is publication output. Research outputs can be disseminated in many different ways, but for the purpose of this report, we focused the analysis on research articles published in journals indexed in Scopus. This type of publication output was chosen because:

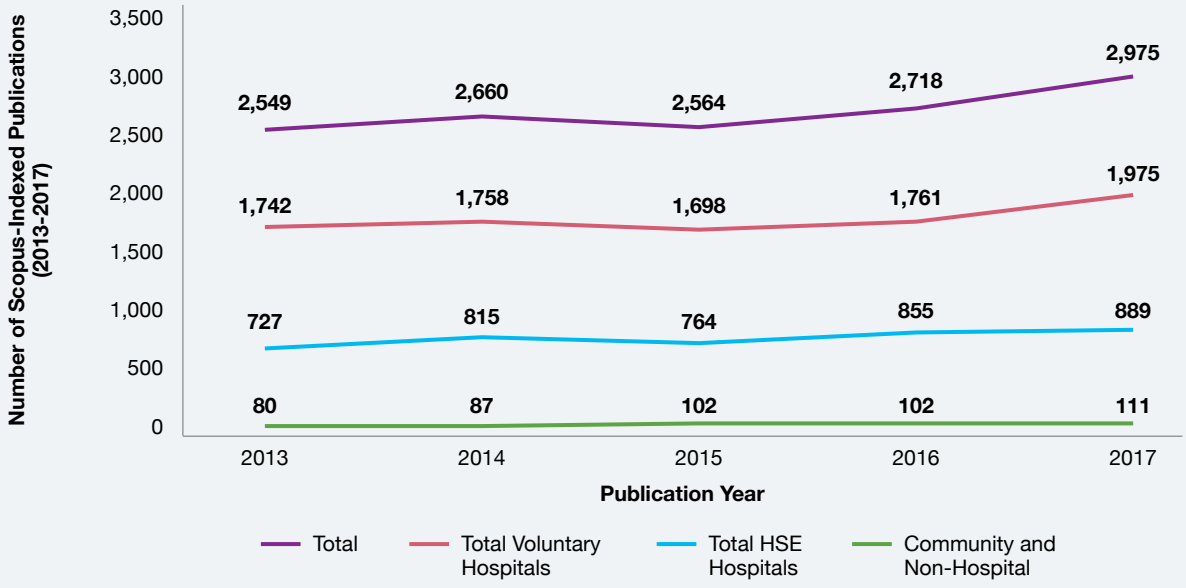
- Indexation is considered to be a validation of the quality of a given journal, indicating that it publishes high-quality research articles.
- Scopus is the Elsevier abstract and citation database and indexes journals from the fields of science, technology, medicine, social sciences, arts and humanities. It also provides research analysis and tracking tools. This database includes over 36,000 titles and over 11,000 publishers, of which over 34,000 are peer-reviewed journals in top-level fields, including life sciences and health sciences.

Trends over time were analysed for journal articles published between 2013 and 2017. The analysis of Scopus indexed publications was carried out using SciVal, a bibliometric tool that uses Scopus data to analyse the research performance of individuals, groups or institutions. As there is no HSE publication policy, hospital publications were generally not affiliated with the HSE but to individual hospitals or CHOs. In order to use the SciVal tool, the hospital datasets were extracted from Scopus individually, curated and then imported into SciVal for analysis.

## 5.1. Analysis of Publication Number per year from 2013-2017

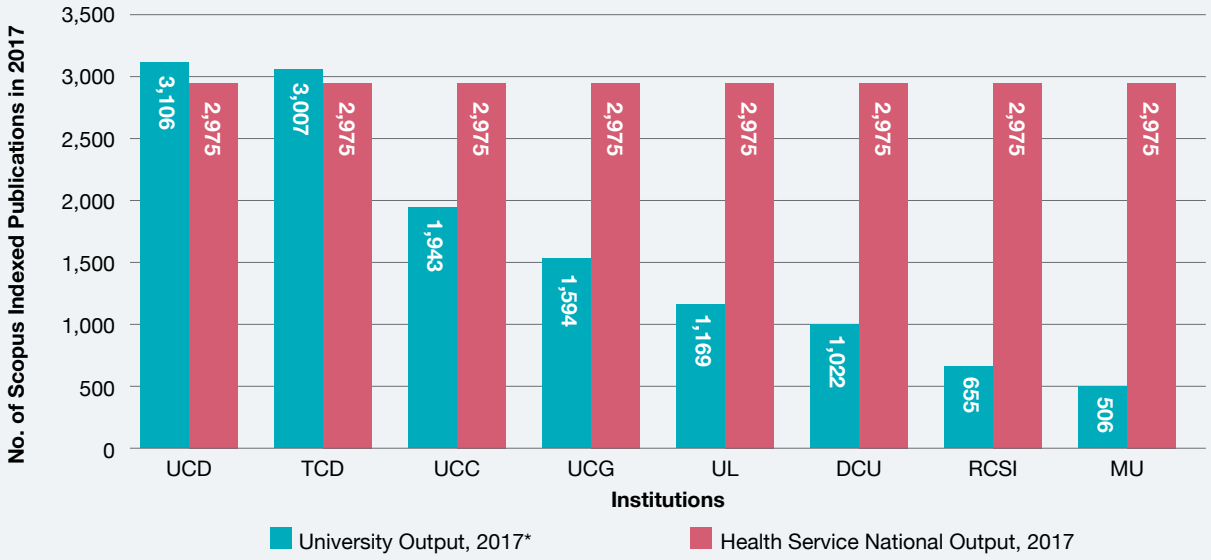
**The total number of publications from HSE organisations and section 38 hospitals nationally** indexed in Scopus **in the five year period from 2013 to 2017 was 13,466** (this includes total HSE Hospitals, n = 4,050; total Voluntary Hospitals, n = 8,934; and total Community and Non-Hospital, n = 482, where at least one of the authors has known HSE affiliation). The figures include the publication output of medical consultants with an academic appointment. **There has been a slight steady increase since 2013** in the total number of publications from the health service (Figure 35), although **community and non-hospital research only account for between 3 to 4% of the total output each year.** This may indicate that much research is not published or is published in other (non-peer reviewed) outlets.

Figure 35: Total number of publications between 2013 and 2017 by HSE Hospitals, Voluntary Hospitals, Community & Non-Hospital and Total



From an annual perspective, **the total number of journal articles published nationally in 2017 was 2,975.** This is comparable to the total output (all disciplines) of some Irish universities like TCD* or UCD* in one single year (Figure 36).

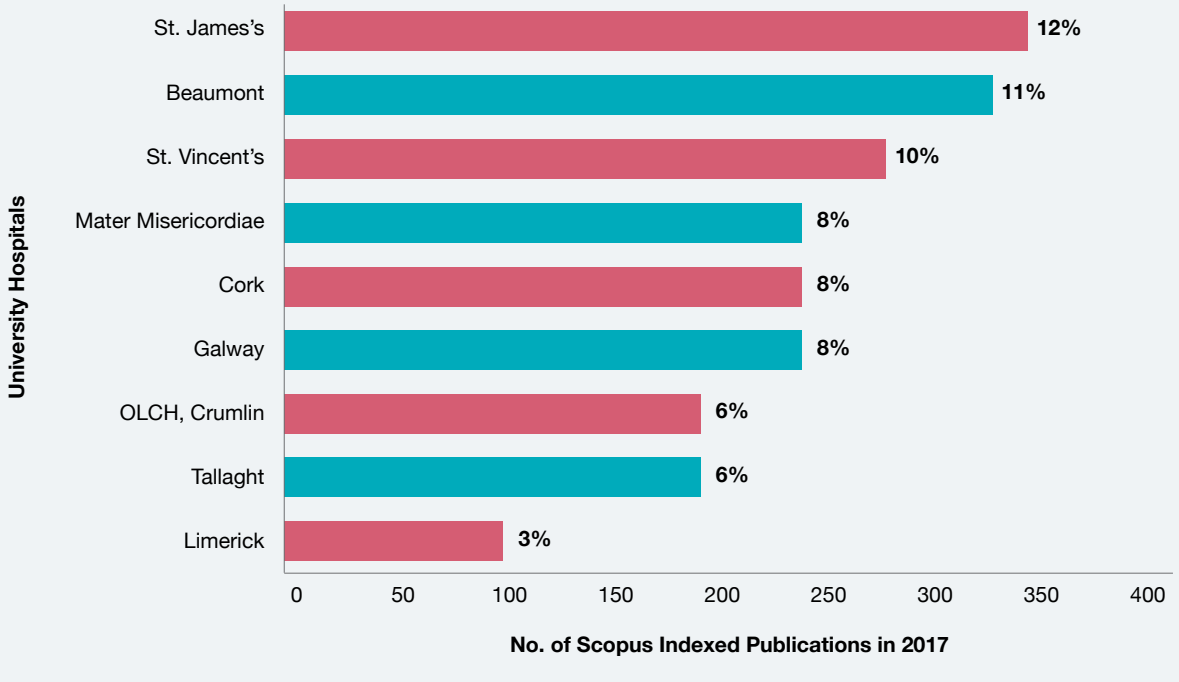
Figure 36: Comparison of 2017 Scopus indexed publications between the health services nationally and the university sector.




* Note that only publications with a university affiliation are captured here, it excludes associated affiliations (i.e. hospitals, institutes)

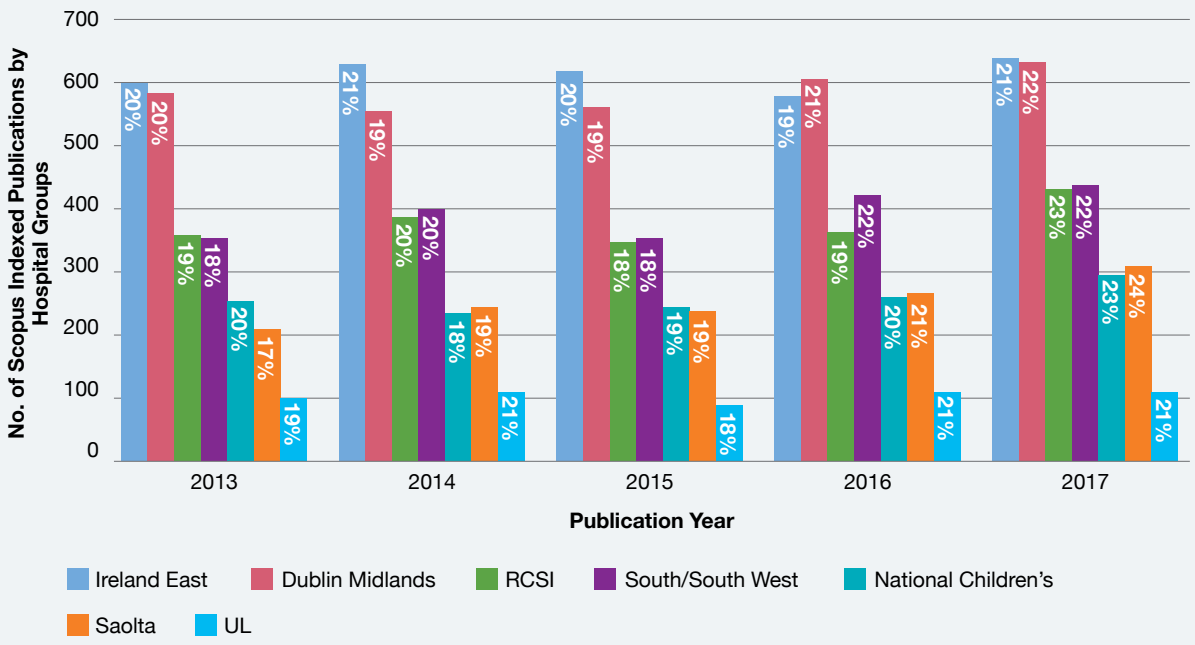
The total number of publications by hospitals in 2017 was 2,864. **Nine out of the 50 public hospitals accounted for three-quarters of the overall hospital publication output; 73% (n = 2,103)** (Figure 37), which may indicate the close association with the academic sector as they are all teaching hospitals.

Figure 37: Hospitals with a publication output of 100 or more journal articles in 2017



The publications were analysed by Hospital Group (Figure 38), and the pattern was consistent across all five years, **with Dublin Midlands Hospital Group and Ireland East Hospital Group having the highest number of publications.**

Figure 38: Scopus indexed publication output per hospital group per year from 2013-2017




Publication ratios for each hospital group were also calculated by dividing the total number of publications of a hospital group by the number of staff per hospital group. **When comparing the publication ratios, the Children's Hospital Group showed the highest relative output.**

## 5.2. Analysis of overall publication output by topic and research activity type

To enable a more complete analysis of the types of health research being conducted in the HSE and funded organisations, a subset of the Scopus-indexed publications, related to 2017 only, were coded using the UK Health Research Classification System. In 2017, there were 2,975 publications in total.

**The top research topics (Figure 39) were Generic Health Relevance26 (17%), followed by Cancer (15%), Cardiovascular (9%), Neurological (8%) and Reproductive Health and Childbirth (7%) research.**

**Treatment Evaluation (Figure 40) represented nearly half of the total research activity type of publications in 2017 (43%), followed by Aetiology (27%), Health Services (14%), Detection and Diagnosis (8%) and Disease Management (3%).**

26 Generic Health relevance refers to research applicable to all diseases and conditions or to general health and wellbeing of individuals, public health research, epidemiology and health services research that is not focused on specific conditions.

Figure 39: Percentage and number of Scopus indexed publications in 2017 by top six health categories nationally

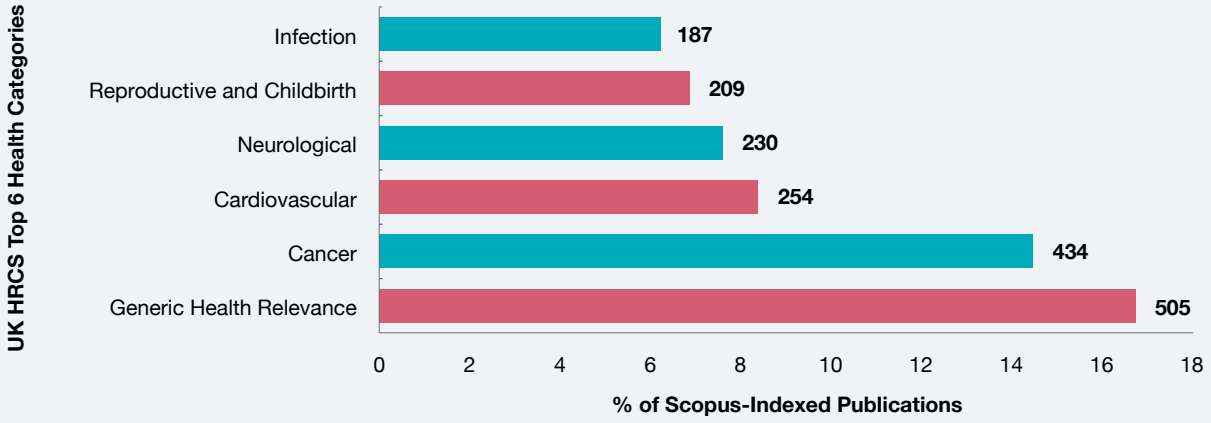
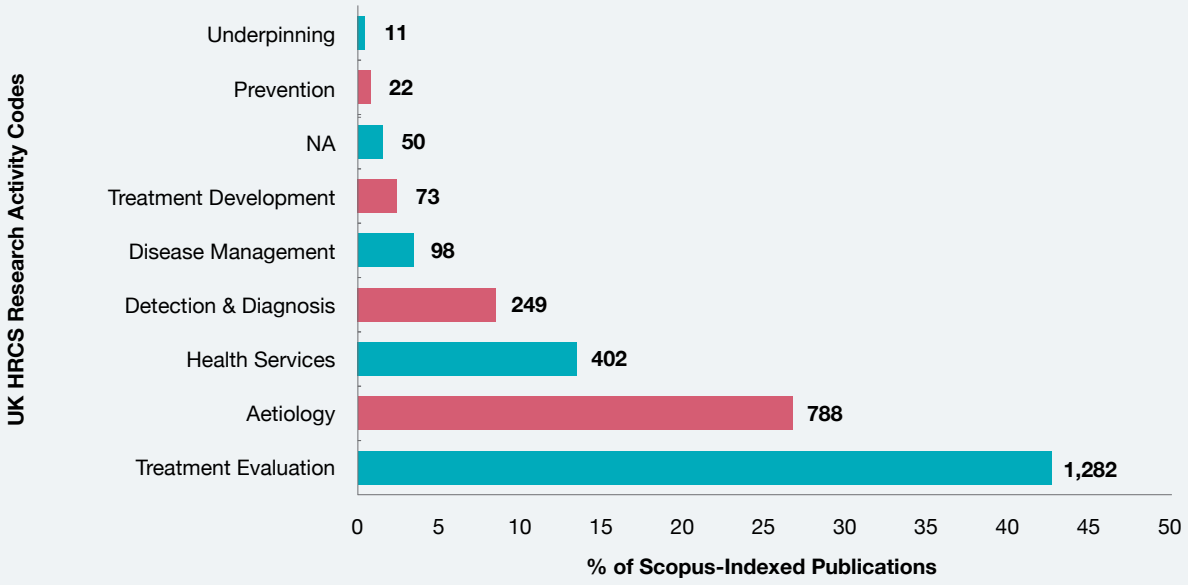



Figure 40: Percentage and number of Scopus indexed publications in 2017 classified using the UK HRCS research activity codes nationally



### 5.2.1 Topics and research activity type of Community and Non-Hospital Research publications

**Community and non-hospital research only represent 4% of the total publications identified in 2017. The majority of publications related to Mental Health (27.9%), followed by Generic Health Relevance (23%), Infection (10%), Cancer (7%) and Neurological (5%)** (Figure 41). **Treatment Evaluation** (Figure 42) **represented over half of the total research activity of publications in 2017 (54%), followed by Aetiology (20%), Health Services (12%),** not applicable/ relevant (6%) and Detection and Diagnosis (5%).

Figure 41: Percentage and number of Scopus indexed publications in 2017 by the top six health categories for community and non-hospital areas

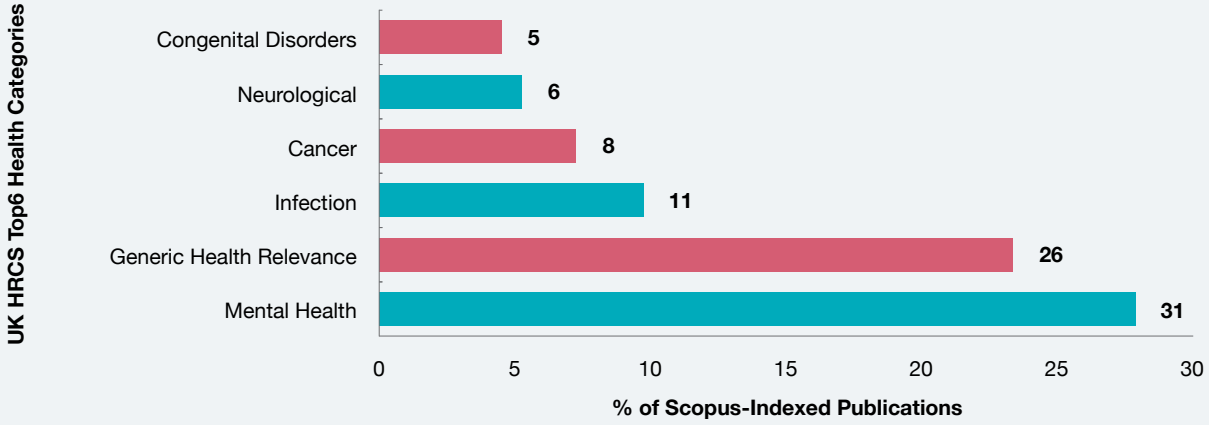
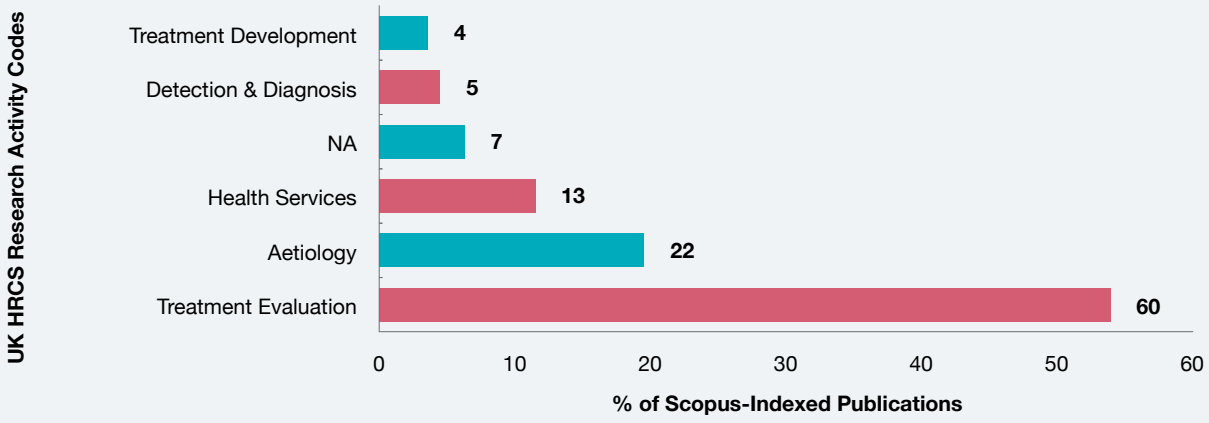



Figure 42: Percentage and number of Scopus indexed publications in 2017 classified using the UK HRCS research activity codes for community and non-hospital areas



### 5.2.2 Hospital research publications – topics and research activity type

Hospital research represented the vast majority of the total publications identified in 2017 (96%), hence the results of the analysis of hospital-based research are very similar to the national total. **The majority of the research was of Generic Health Relevance (17%), followed by Cancer (15%), Cardiovascular (9%), Neurological (8%) and Reproductive Health and Childbirth (7%) research** (Figure 43). **Treatment Evaluation** (Figure 44) **represented nearly half of the total research activity of publications in 2017 (43%), followed by Aetiology (27%), Health Services (14%), Detection and Diagnosis (9%) and Disease Management (3%).**

Figure 43: Percentage and number of Scopus indexed publications in 2017 classified by the top six health categories for total hospitals

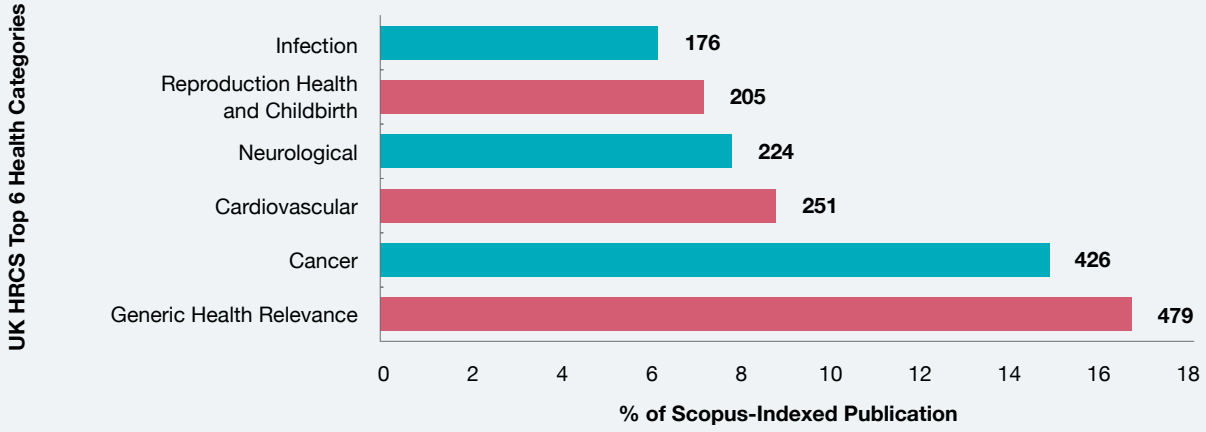
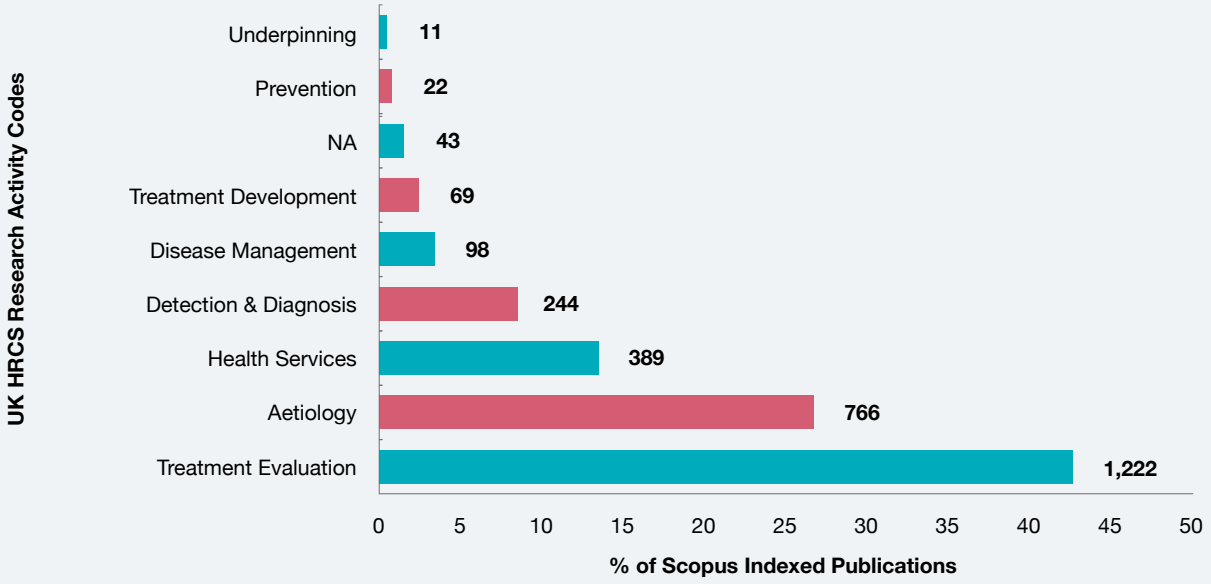


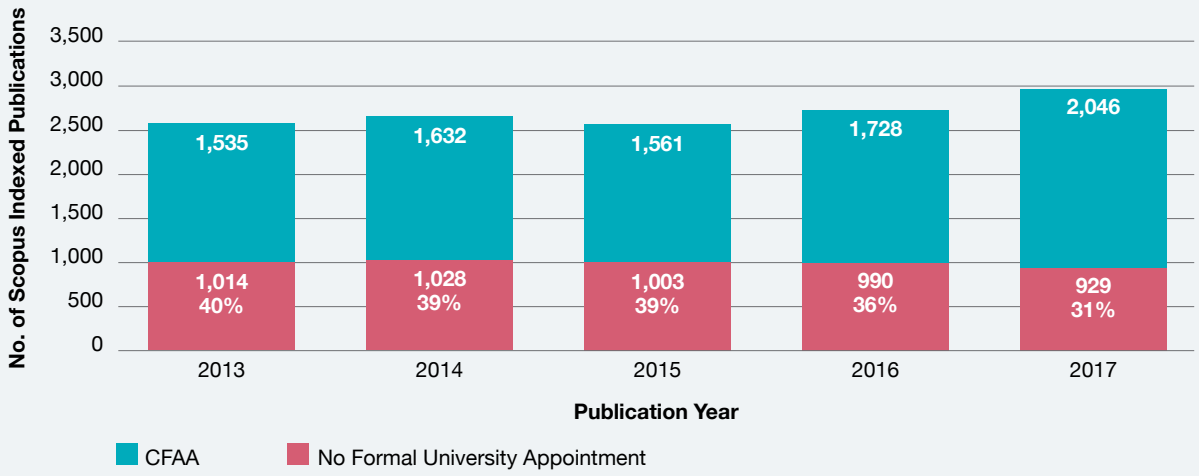

Figure 44: Percentage and number of Scopus indexed publications in 2017 by research activity codes for total hospitals



## 5.3. Analysis of Publications by Medical Consultants with a Formal Academic Appointment

Of the total 13,466 articles published between 2013 and 2017 within the Irish public health system, **4,964 (37%) were published by CFAAs** (Figure 45), which indicates that **the publication output of this cohort is very prolific as they represent only a very small percentage of the total number of existing consultants.**

Figure 45: Scopus indexed CFAA publications indexed in the Scopus database from 2013 to 2017




# Publications

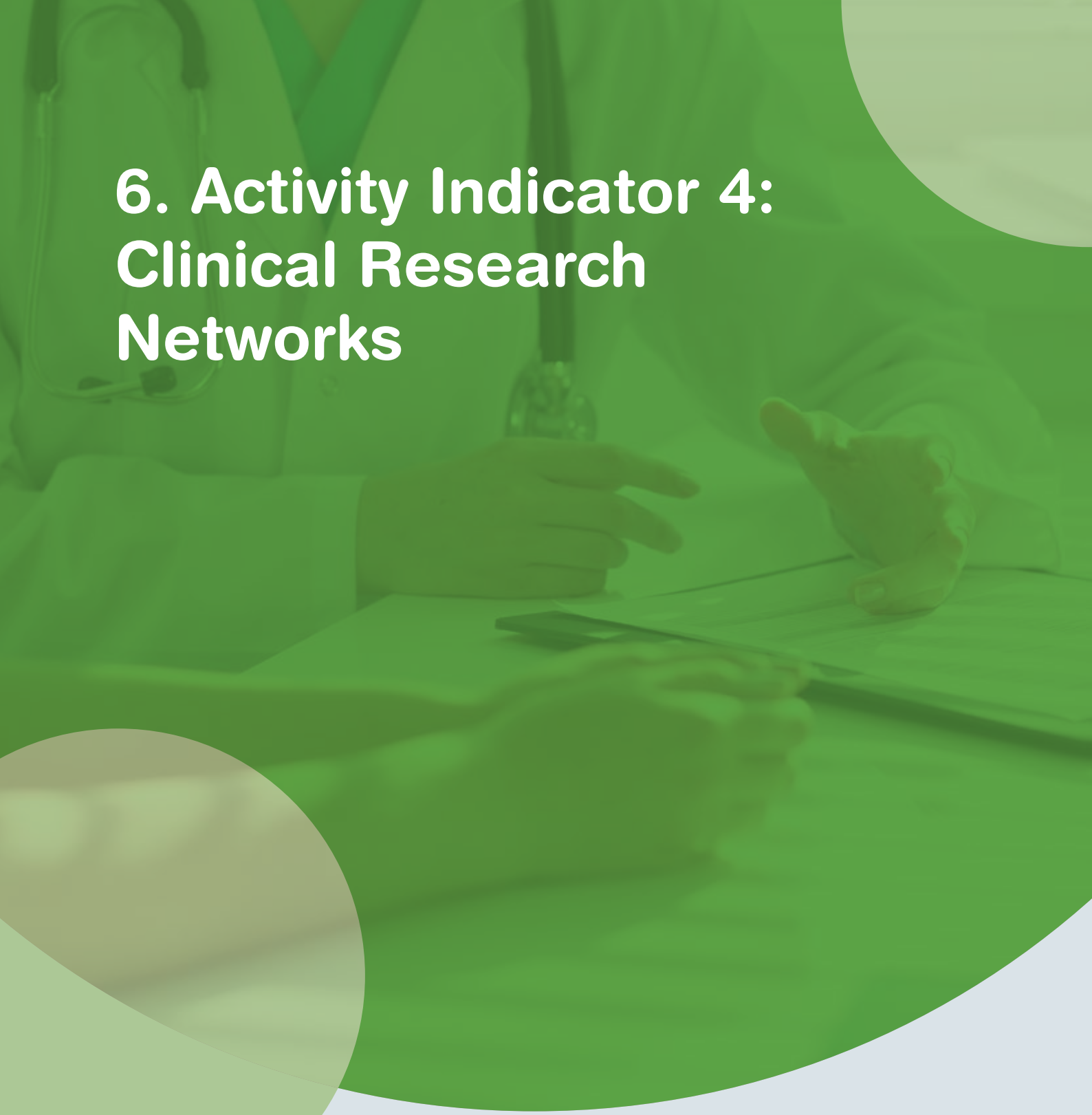
2,975 Publications (in 2017).

13,466 publications between 2013 and 2017. Slight increase year-on-year.

The majority of publications were on topics of 'Generic Health Relevance'.

37% were published by consultants with a formal academic appointment.

The majority of publications were by Hospital-based staff (primarily in Voluntary Hospitals).



# 6. Activity Indicator 4: Clinical Research Networks

For the purpose of this report, Clinical Research Networks are defined as networks of clinicians interested in a particular disease or topic which are devoted to the improved care of patients and health services through research in that particular topic. The existence of these networks indicates a critical mass of research activity in a given thematic area. Some of the networks involve other actors such as academics, scientists, patients, professional bodies, etc.

These networks can be funded in a variety of ways:

- Health Research Board, state funding or other research funding agencies, e.g. Wellcome Trust
- Membership fees
- Fundraising or via an associated charity
- Philanthropic or other funding

This report focuses on networks with a clinical research focus. Other health research networks or centres with a more basic research, translational or academic focus, patient-led networks, professional body networks or academic research centres are outside the scope of this report.

We have classified the Clinical Research Network into two distinct types: Clinical Trial Networks (with a focus on clinical trials and studies) and Collaborative Clinical Research Networks (with a focus on knowledge sharing, dissemination and collaboration).

## 6.1. Clinical Trial Networks (CTNs)

These networks have a strong focus on clinical trials of medicinal products but may also be involved in clinical investigations of medical devices and other clinical studies. Those involved in regulated clinical trials require significant funding and infrastructure to manage their regulatory, financial and oversight requirements and are often funded by the HRB.

This group includes the following networks:

- Cancer Trials Ireland (CTI)
- Blood Cancer Network Ireland (BCNI)
- HRB Critical Care Clinical Trials Network Ireland (HRB CCTNI)
- HRB Mother & Baby Clinical Trials Network Ireland (CTNI)
- HRB Primary Care Clinical Trial Network Ireland (Primary Care CTNI)
- Investigator Network for Inflammatory Bowel Disease Therapy in Ireland (INITIative)
- Irish Hepatitis C Outcomes Research Network (ICORN)
- The Vasculitis Irish Network (VINE)
- Respiratory and Asthma Research Network (INCA)
- Neurology Research Group in St. Vincent's University Hospital/ SVUH

Further detail on these networks is included in Table 8.

Table 8: Clinical trial Networks in Ireland

| Primary Topic | Network Name/ Acronym/ Start Date | Membership | Core funding | Aim |
|---|---|---|---|---|
| Cancer | Cancer Trials Ireland / CTI<br>1996 | 17 Cancer Trial Research Units in Cork, Limerick, Offaly, Galway, Sligo, Donegal, Waterford and Dublin.<br>Members: Almost all cancer treating specialists in Ireland are Members of CTI (98%). | HRB, Irish Cancer Society, grant income, monitoring income. | CTIs vision is to be able to provide every patient with cancer, access to potentially high-quality and life-altering cancer trials and make Ireland a highly attractive location to open cancer trials.<br>CTI's mission is to discover new diagnostics and treatments that will extend and enhance the lives of the millions of people who are diagnosed with cancer each year. |
| Blood Cancer | Blood Cancer Network Ireland / BCNI<br>2015 | NUI Galway/ UHG, UCC/ CUH, TCD/ SJH, The National Cancer Registry Ireland, Beaumont Hospital and The Mater Hospital | SFI and ICS | The aim of BCNI is to provide Irish blood cancer patients with access to novel and innovative cancer treatments through the provision of early phase clinical trials, offering the opportunity to test new, potentially life-saving treatments and drugs. The network also collects information and samples from blood cancer patients in Ireland in order to improve their understanding and to uncover new ways to combat this disease. |
| Critical Care | HRB Critical Care Clinical Trials Network Ireland (HRB CCTNI)<br>2015 | The network encompasses more than 75% of all the ICU capacity in Ireland. | HRB | The HRB CCTNI brings together doctors, nurses and researchers to test new treatments that can improve outcomes for critically ill patients in intensive care units. |
| Perinatal health | HRB Mother & Baby Clinical Trials Network Ireland (CTNI)<br>2015 | The members include researchers, consultants, obstetricians, neonatologists, midwives and related professionals from seven of the largest maternity hospitals in Ireland. | HRB | The aim of the CTNI is to address problems in women and children's health that will have a global impact. CTNI has a well-established record in collaborative research and in conducting large-scale, multicentre, randomised controlled trials. |
| Primary Care | HRB Primary Care Clinical Trial Network Ireland (Primary Care CTNI)<br>2015 | NUI Galway, RCSI & QUB and ICGP with many GPs and other primary care health professionals. | HRB | Its aims are the design, conduct and dissemination of high quality, internationally recognised, randomised trials in Irish primary care, which address important and common problems. |

| Primary Topic | Network Name/ Acronym/ Start Date | Membership | Core funding | Aim |
|---|---|---|---|---|
| Inflammatory Bowel Disease | Investigator Network for Inflammatory Bowel Disease Therapy in Ireland / INITIative | Clinical and scientific investigators with an interest in Crohn's Disease and Ulcerative Colitis throughout the island of Ireland | Not available | It aims to foster collaboration and encourage multi-centre investigator-initiated studies in Crohn's Disease and Ulcerative Colitis in Ireland. |
| Hepatitis C | Irish Hepatitis C Outcomes Research Network / ICORN<br>2012 | Collaboration between Clinicians from Beaumont Hospital, CUH, GUH, the Mater Hospital, St. Luke's Hospital, Kilkenny, SJH and SVUH, patient advocacy groups and healthcare service providers including ISGE, IDSI, and the NCPE. | AbbVie Ireland and Bristol Myers Squibb | The initial goal of this collaboration was to optimise the quality of care of patients with Hepatitis C (HCV) undergoing treatment with direct-acting antiviral therapy (DAAs). Other network research themes developed since 2012 include innovative research studies on models of care and screening for HCV infection. |
| Vasculitis | VINE / The Vasculitis Irish Network<br>2012 | SJH/ TUH, SVUH, OLCHC, CUH, GUH, Southern Health & Social Care Trust, UK and Vasculitis Ireland Awareness. | HRB, Vasculitis Ireland, | The network is comprised of dedicated multi-disciplinary centres that provide a coordinated care-path for patients with primary systemic small vessel vasculitis (PSV), from diagnosis to relapse and on to long term remission. It provides access to clinical trials for patients with PSV. |
| Respiratory | Respiratory and Asthma Research Network / INCA Studies<br>2011 | A collaborative research programme delivered from the RCSI Research Centre and TCD Bioengineering. | SFI | The focus is on clinical investigations for respiratory devices, particularly developing a novel technology which can be used in clinical practice as an objective assessment of patient adherence to inhaled therapy. |
| Neurology | Neurology Research Group in SVUH<br>2003 | UCD and SVUH | SFI, HRB and industry | Their areas of excellence are in neuroinflammatory disorders, in particular, multiple sclerosis, movement disorders and cognitive neurology. The focus is on running numerous clinical pharmaceutical trials, academic research studies – both clinical and basic science, and interventional studies with allied health professionals. Several national neurology registries and research databases are also coordinated from the SVUH site. |

The performance of a clinical trial requires a great deal of support and infrastructure. A number of organisations, many generally funded by the Health Research Board, provide significant support for this activity:

## HRB Clinical Research Coordination Ireland (CRCI)[27]

HRB-CRCI provides support for clinical trials undertaken in the university associated **Clinical Research Facilities / Centres** (CRF/Cs). Characteristics and information on each CRF/C can be found in Table 4 of Appendix 3.

The HRB-CRCI services and activities include being the central point of contact for sponsors looking to start a trial, streamlining national processes for feasibility studies, improving study start-up timelines for study setup, recruitment tracking and collation of metrics, provision of advice in relation to regulatory pathways and research ethical approval, and audit and monitoring, among others.

HRB-CRCI is hosted by **Clinical Research Development Ireland** (CRDI)[28], which is a not-for-profit research partnership comprising NUI Galway, RCSI, TCD, UCC, UCD, and UL, their medical schools, associated academic hospitals and CRFs, with the objective of accelerating the translation of biomedical research into improved diagnostics, therapies and devices for patients. It was formally launched by the Minister for Health on October 2nd, 2017. CRDI builds on the achievements of Molecular Medicine Ireland which was established in 02 October, 2017.

## HRB Trials Methodology Research Network (TMRN)[29]

The HRB-TRMN is a new, collaborative initiative between a number of Irish and international higher education institutes and methodology centres. It is funded by the HRB and will provide direct support in two ways, firstly through the development of a Clinical Trial Expertise Database (C-TED) and also through the Trial Methodology and Reporting Advisory Service (TMRAS).

## Cancer Trials Ireland (CTI)[30]

CTI provides supports for oncology clinical trials within the Oncology Clinical Trial units across 14 public and three private hospital sites in Cork, Limerick, Offaly, Galway, Sligo, Donegal, Waterford and Dublin. It is a not-for-profit organisation with charitable status. Services provided include planning, opening, co-coordinating, supporting, monitoring and auditing cancer trials in Ireland. In addition, the organisation provides training facilitates, co-operation between all professionals working in the area, and supports the development of cancer trials research units around the country.

## Cross-border Healthcare Intervention Trials in Ireland Network (CHITIN)

The CHITIN initiative was launched in September 2018 and is a unique cross-border partnership between the Public Health Agency in Northern Ireland and the Health Research Board in the Republic of Ireland, to develop infrastructure and deliver healthcare intervention trials in health and social care. The initiative will help prevent and cure illness, and promote improved health and wellbeing in Northern Ireland, Ireland and Irish cross-border areas. It will also enhance all-Ireland partnerships for researchers and health professionals.

27 https://www.hrb-crci.ie/

28 https://www.crdi.ie/

29 https://www.hrb-tmrn.ie/

30 http://www.cancertrials.ie/

## 6.2. Collaborative Clinical Research Networks

The focus of these clinical networks is mainly on attracting clinicians and other professionals interested in a particular disease or topic for the purpose of improving understanding, and the sharing of knowledge and research expertise. They can also be focused on the development of disease registries or biobanks. Table 9 includes further detail on these networks*.

Table 9: Collaborative Clinical Research Networks

| Primary Topic | Network Name/ Acronym/ Start Date | Membership | Core funding | Aim |
|---|---|---|---|---|
| Neurology / Pain | Irish Pain Research Network (IPRN)<br>2015 | Healthcare professionals and scientists, with expertise in pain management. | Irish Pain Society and other funders. | This network aims to bring together all active pain researchers on the island of Ireland (North and South) for the purposes of sharing research results and ideas and facilitating cross-institutional collaboration in the area of pain research. |
| Mental Health | Irish Psychosis Research Network (IPRN) | RCSI, TCD, St Patrick's Hospital, UCC, NUI Galway, QUB and UCD. | RCSI, SFI and HRB. | The network aims to share current knowledge and new discoveries about the causes of, and treatment for, psychotic disorders. Research areas include disorders that affect perception, cognition and mood in ways that are challenging and, at times, disabling for those affected. |
| Diabetes | Galway Diabetes Research Centre (GDRC)<br>2012 | NUI Galway and Saolta University Health Care Group. | SFI and HRBs. | The centre is a hub for collaborative effort of researchers and clinicians, with a passion for this work, to provide a greater understanding of how diabetes develops and the underlying mechanisms, the development of new and better therapies for patients, and assessing healthcare interventions and delivery for patients. |
| Arthritis | Arthritis Research Coalition<br>2016 | SVUH, GUH, LUH, OLCHC, Mater Hospital, CUH and Beaumont Hospital. | Arthritis Ireland and the HRB – CRCI. | The primary aim of the biobank is to recruit patients with common rheumatic diseases, and to obtain bio-samples that will underpin clinical research. A secondary aim is to increase national involvement in clinical trials of novel therapeutic agents. |

* Health research networks or centres with a more basic research, translational or academic focus, patient-led networks, professional body networks or academic research centres are outside the scope of this report.

# 7. Conclusions

This report is the first benchmark of research activity in publicly funded health and social care services in Ireland. The process of information gathering was laborious and highlighted the lack of information systems and infrastructure to support the collection of meaningful research related metrics. Hence, a large portion of the analysis has been possible only thanks to the generosity of all the entities that contributed information, such as the RECs, the HRB, the HPRA, the various Clinical Trial Networks, Universities and of course the Health Service staff who responded to the survey.

Despite the diversity of datasets, sometimes incomplete or imperfect, and the impossibility of linking them to obtain a clearer picture, this analysis provides a reasonable snapshot of research activity in the health service in recent times against which future progress can be measured. The information has been presented around four research activity indicators; people, projects, publications and networks. More sophisticated key performance indicators traditionally used for research in other settings (i.e. research funding, etc.) could not be used due to the lack of available information.

This study shows that the HSE and its funded organisations are research active. Staff members engaged in research are distributed across the service in hospitals, the community and corporate services, and although the majority of research active staff belong to the clinical professions (medical doctors, nurses and midwives, and health and social care professionals), there are also research active staff among the administration and management categories.

While research active staff exist in both hospital and community based services (i.e. 40% of staff survey respondents were hospital based and 31% were community based), the peer reviewed publication output (indexed in Scopus) was mainly authored by hospital based staff. This may indicate that community-based staff engaged in research may disseminate their results via different outlets rather than via peer-review publications indexed in Scopus (i.e. presentation at conferences, non-peer reviewed publications, internal reports, etc.), may not publish their research outputs or may do so by co-authoring with hospital-based staff.

The survey also indicated that a large proportion of respondents (37%) were from the Health and Social Care professions. However, when the number of respondents was compared to the total number of professionals in each category, the proportional response from medical doctors was the highest. This may indicate that it is more common for medical doctors to be research active than it would be for staff in the Health and Social Care or the Nursing and midwifery professions.

Interestingly, over a quarter of survey respondents were based in the Dublin Midlands Hospital Group (230) and CHO7 (261). Dublin Midlands Hospital Group was also one of the Hospital Groups with the largest publication output (with St. James Hospital being the top performer), together with the Ireland East Hospital Group (with St. Vincent's and the Mater Hospital being the top performers of the group). Understandably, the publication output of teaching hospitals closely associated with university partners was the greatest. Interestingly, nearly three-quarter of all publications in 2017 were produced by nine hospitals, and for the most part, although not always, the hospitals with larger publication output also had the larger number of consultants with joint academic appointments. This was not the case for Our Lady's Children's Hospitals Crumlin however, which only had five joint appointments but had a significant publication output. On the other hand, Connolly Hospital had 11 joint appointments but was not one of the top nine publication performers (i.e. with over 100 publications per year).

Medical consultants with an academic appointment represent 7% of all consultants, but are responsible for 37% of the publication of journal articles indexed in the Scopus database, and were in receipt of 30% of the total HRB funding in 2017. These joint posts therefore appear to be a key driver of research activity. However the vast majority of health service staff do not have an academic affiliation, and have therefore no access to supports offered by the academic sector. In spite of the lack of other support mechanisms and time availablility, their involvement in research and research output are admirable; 60% of survey respondents had no linkage (formal or otherwise) with the academic sector, and 63% of publications were authored by staff without formal academic appointments. The survey also indicates that many staff carry out research after working hours on top of their normal clinical duties, which shows the commitment of research active staff to this activity.

The most prevalent research topic nationally, both for research projects and for publications was “generic health relevance”. This is research that is applicable to all diseases and conditions. Cancer was the second most common research topic as determined by analysis of the REC approved studies, regulated clinical trials, HRB awards and publications; with most studies relating to the evaluation of cancer treatment. This may relate to the existence of Cancer Trials Ireland, which over the years has had a key role in supporting cancer clinical trials and studies in Ireland. Cancer was the second most prevalent topic of publications from hospital based staff, while mental health was the priority topic of publications from community based staff.

The analysis of the data provided by the research ethics committees provides interesting insights into the volume of project approvals on an annual basis and the topics of interest. This analysis has to be considered in the context that non-regulated clinical studies involving multiple sites require multiple approvals for a single project. Half of all approvals were related to the evaluation of treatments and health services research. Regional analysis of project approvals showed large differences in the regional REC service provision: the South/South-West region reviewed over a quarter of the total number of projects with only one REC, while the East region reviewed a similar number of proposals but had 20 hospital based RECs, and lacks a REC to review CHO based research in the area.

Due to the fact that multi-site studies must be approved by multiple RECs, the total number of project approvals at national level is, therefore, larger than the total number of projects, which unfortunately could not be specifically determined. As the total number of approvals was over 1,800, we can only conclude that the total number of projects starting in 2017 was less than that. As only 27 regulated clinical trials and nine regulated clinical investigations commenced in that year, the data implies that the majority of the projects approved involved non-HPRA regulated research.

A simple comparison of the number of clinical trials in other countries of similar size to Ireland, such as Denmark and Finland, indicates that there is significant room for improvement in Ireland. Over the last 10 years a significant amount of investment in the development of clinical research networks and clinical research infrastructure has taken place, and much of this investment has taken place via the academic sector. As shown in chapter 6, a significant amount of networks and infrastructure currently exist to support clinical research, but yet the health service is underperforming in this regard when compared to other EU countries.

The analysis of EU grants involving the HSE as a participant shows that this is a missed opportunity. Only six projects were awarded to the HSE in 2017, which received a marginal part of the overall total awarded project funding. Also, while the HSE is also actively involved in commissioning research related services from the third level sector in Ireland, only €6 million was invested in this activity in 2017, which seems very small considering the evidence requirement of such a large health service and the links that already exist with the university sector.

Overall, this study shows that a significant percentage of staff in the HSE and its funded organisations are research active, and the outputs cannot be underestimated. Despite the fact that research is, by an large, not formally embedded within the process of service delivery, it is very much part of the on-going activity in the health service, and it cannot be ignored. The data in this study shows the huge potential for impact that could be leveraged by aligning research activity to service needs, in order to obtain the maximum benefit for our health service, and the health and wellbeing of our patients and the general population.

# Appendices

# Appendix 1: UK HRCS category descriptions

Table A 1: UK Health Research Classification System Health Categories

| | Category | Description |
|---|---|---|
| 1 | Blood | Haematological diseases, anaemia, clotting (including thrombosis and venous embolisms) and normal development and function of platelets and erythrocytes |
| 2 | Cancer | All types of neoplasms, including benign - malignant cancers (includes leukaemia) |
| 3 | Cardiovascular | Coronary heart disease, diseases of the vasculature and circulation including the lymphatic system, and normal development and function of the cardiovascular system |
| 4 | Congenital Disorders | Physical abnormalities and syndromes that are not associated with a single type of disease or condition including Down's syndrome and cystic fibrosis |
| 5 | Ear | Deafness and normal ear development and function |
| 6 | Eye | Diseases of the eye and normal eye development and function |
| 7 | Infection | Diseases caused by pathogens, acquired immune deficiency syndrome, sexually transmitted infections and studies of infection and infectious agents |
| 8 | Inflammatory and Immune System | Rheumatoid arthritis, connective tissue diseases, autoimmune diseases, allergies and normal development and function of the immune system |
| 9 | Injuries and Accidents | Fractures, poisoning and burns |
| 10 | Mental Health | Depression, schizophrenia, psychosis and personality disorders, addiction, suicide, anxiety, eating disorders, learning disabilities, autistic spectrum disorders and studies of normal psychology, cognitive function and behaviour |
| 11 | Metabolic and Endocrine | Metabolic disorders (including Diabetes) and normal development and function. Includes all research on pineal, thyroid, parathyroid, pituitary and adrenal glands. |
| 12 | Musculoskeletal | Osteoporosis, osteoarthritis, muscular and skeletal disorders and normal musculoskeletal and cartilage development and function |
| 13 | Neurological | Dementias, transmissible spongiform encephalopathies, Parkinson's disease, neurodegenerative diseases, Alzheimer's disease, epilepsy, multiple sclerosis and studies of the normal brain and nervous system |
| 14 | Oral and Gastrointestinal | Inflammatory bowel disease, Crohn's disease, diseases of the mouth, teeth, oesophagus, digestive system including liver and colon, and normal oral and gastrointestinal development and function |
| 15 | Renal and Urogenital | Kidney disease, pelvic inflammatory disease, renal and genital disorders, and normal development and function of male and female renal and urogenital system |
| 16 | Reproductive Health and Childbirth | Fertility, contraception, abortion, in vitro fertilisation, pregnancy, mammary gland development, menstruation and menopause, breastfeeding, antenatal care, childbirth and complications of new-borns |

| | Category | Description |
|---|---|---|
| 17 | Respiratory | Asthma, chronic obstructive pulmonary disease, respiratory diseases and normal development and function of the respiratory system |
| 18 | Skin | Dermatological conditions and normal skin development and function |
| 19 | Stroke | Includes both ischaemic (blood clots) and haemorrhagic (cerebral haemorrhage) strokes |
| 20 | Generic Health Relevance | Research applicable to all diseases and conditions or to general health and wellbeing of individuals. Public health research, epidemiology and health services research that is not focused on specific conditions. Underpinning biological, psychosocial, economic or methodological studies that are not specific to individual diseases or conditions |
| 21 | Disputed Aetiology and Other | Conditions of unknown or disputed aetiology (such as chronic fatigue syndrome/ myalgic encephalomyelitis), or research that is not of generic health relevance and not applicable to the top 19 specific health categories listed above |

Table A 2: UK Health Research Classification System Research Activity Codes

| | Category | Description |
|---|---|---|
| 1 | Underpinning Research | Research that underpins investigations into the cause, development, detection, treatment and management of diseases, conditions and ill health |
| 2 | Aetiology | Identification of determinants that are involved in the cause, risk or development of disease, conditions and ill health |
| 3 | Prevention of Disease and Conditions, and Promotion of Well-Being | Research aimed at the primary prevention of disease, conditions or ill health, or promotion of well-being |
| 4 | Detection, Screening and Diagnosis | Discovery, development and evaluation of diagnostic, prognostic and predictive markers and technologies |
| 5 | Development of Treatments and Therapeutic Interventions | Discovery and development of therapeutic interventions and testing in model systems and preclinical settings |
| 6 | Evaluation of Treatments and Therapeutic Interventions | Testing and evaluation of therapeutic interventions in clinical, community or applied settings |
| 7 | Management of Diseases and Conditions | Research into individual care needs and management of disease, conditions or ill health |
| 8 | Health and Social Care Services Research | Research into the provision and delivery of health and social care services, health policy and studies of research design, measurements and methodologies |

# Appendix 2: UK HRCS by HSE Region

Table A 3: UK Health Research Classification System – Research Categories of REC approved studies per region.

| HRCS Health Categories | East* | South/ South West | West/ North-West | Mid-Western | South East | Midlands | North East | TOTAL |
|---|---|---|---|---|---|---|---|---|
| Generic Health Relevance | 106 | 111 | 89 | 58 | 14 | 10 | 6 | **393** |
| Cancer | 46 | 70 | 34 | 13 | 12 | 3 | 2 | **180** |
| Reproductive Health and Childbirth | 57 | 58 | 17 | 7 | 5 | | 3 | **147** |
| Mental Health | 49 | 48 | 34 | 17 | 17 | 9 | 6 | **179** |
| Cardiovascular | 36 | 21 | 53 | 13 | 2 | 1 | | **126** |
| Neurological | 48 | 49 | 13 | 5 | 4 | | | **119** |
| Metabolic and Endocrine | 30 | 22 | 21 | 12 | | | 1 | **86** |
| Musculoskeletal | 29 | 21 | 22 | 3 | 3 | | | **78** |
| Oral and Gastrointestinal | 22 | 23 | 8 | 2 | | | | **55** |
| Infection | 25 | 16 | 15 | 5 | 4 | 1 | | **66** |
| Inflammatory and Immune System | 31 | 23 | 10 | 3 | 1 | 1 | 1 | **70** |
| Other | 12 | 13 | 4 | 2 | | 4 | | **35** |
| Respiratory | 12 | 10 | 10 | 3 | | | | **35** |
| Eye | 16 | 5 | 5 | 1 | 5 | | | **32** |
| Blood | 14 | 10 | 2 | 2 | 2 | 2 | | **32** |
| Renal and Urogenital | 9 | 2 | 8 | 4 | | | 2 | **25** |
| Stroke | 8 | 6 | 7 | 1 | 1 | | | **23** |
| Congenital Disorders | 16 | 9 | 2 | 5 | | | | **32** |
| Skin | 17 | 5 | 7 | | 2 | 1 | | **32** |
| Injuries and Accidents | 7 | 4 | 2 | 1 | | | | **14** |
| Ear | 7 | | 0 | | | | | **7** |
| NA | | | 4 | 0 | | | | **4** |
| | **597** | **526** | **367** | **157** | **72** | **32** | **21** | **1772** |

* Studies approved by Beaumont Hospital and Daughters of Charity RECs not included.

# Appendix 3: Clinical Research Facilities (CRFs) and Clinical Research Centres (CRCs)n

The CRF and CRC provide "infrastructure, physical space and facilities, experienced research and specialist support staff and the necessary quality and oversight programmes that are critical for the successful conduct of world-class patient-focused research". Research in CRFs and CRCs is supported by Clinical Research Coordination Ireland (Table A4):

As per 2018, the following CRFs/CRCs exist:

- HRB CRF Cork at University College Cork and Mercy University Hospital
- HRB CRF Galway at University Hospital Galway
- Royal College of Surgeons Ireland CRC at Beaumont Hospital
- University College Dublin CRC at Mater Misericordiae University Hospital and St. Vincent's University Hospital
- Wellcome Trust – HRB CRF at St. James's Hospital
- National Children's Research Centre at Our Lady's Children's Hospital Crumlin
- Health Research Institute (HRI) Clinical Research Support Unit (CRSU) at the University of Limerick and University Limerick Hospitals

The CRF/Cs are committed to providing state-of-the-art facilities and equipment to facilitate research in partnership with academia and the commercial sector, in order to gain a better understanding of how drugs work on humans, and to develop life-enhancing therapies through clinical trials and basic research. Research carried out at these locations aims to find breakthroughs in drug treatments, food therapies, food supplementations and medical devices, which will be converted into better and safer treatments for patients. Patient-focused research is top of the agenda. The units facilitate a wide range of researchers in conducting clinical trials, observational studies and the collection of biological materials in areas such as experimental medicine, early and late phase clinical trials, and, studies by allied health professionals.

The structures and set-up of the CRFs/Cs vary from institution to institution and are often co-located on a hospital site rather than the main university campus. CRFs/Cs support institutional sponsored trials, industry-sponsored trials, investigator-led trials, regulated and non-regulated trials. They support a variety of personnel including investigators, researchers (including trial nurses), clinicians, honorary appointees, project managers, biomedical engineers, translational scientists, industry sponsors and other research support staff.

Table A 4: A summary of Clinical Research Facilities/ Centres across Ireland and Northern Ireland

| No. | Facility/ Centre Funder | Institution(s) | Established | Director | Coverage | Core Team | Studies |
|---|---|---|---|---|---|---|---|
| 1 | HRB Clinical Research Facility Cork (HRB CRF-C)<br>HRB/ UCC | UCC and MUH, Cork | 2011 | Professor Joseph Eustace | South and South-Western regions of Ireland with a population of over 1 million (greater Munster region) | 69 | 108 Active Studies |
| 2 | HRB Clinical Research Facility, Galway (HRB CRFG)<br>HRB | NUI Galway, GUH Saolta University Health Care Group | 2008 | Professor Martin O'Donnell | West and North region of Ireland with a population of just under 1 million | 58 in CRFG<br>9 in Cancer Clinical Trials Unit (CCTU) | Non-Oncology: 48 active studies<br>CRFG Data Management and Statistics: 16 active studies<br>CCTU: Unknown |
| 3 | Wellcome Trust HRB Clinical Research Facility at SJH (Wellcome Trust HRB CRF SJH)<br>Wellcome Trust and the HRB | TCD and SJH | 2013 | Professor Martina Hennessy | Greater Dublin Midlands area generally. For some specialist areas St. James's is the National Centre for many specialist services (e.g. Haemophilia, Burns, Bone Marrow Transplant, Oesophageal Cancer) | 23 | 41 studies currently open to patient recruitment.<br>53 studies completed and closed since 2013 |
| 4 | RCSI Clinical Research Centre (RCSI CRC)<br>RCSI | RCSI and Beaumont Hospital | 2000 | Professor Dermot Kenny | Greater Dublin/ North East area | 30 | Major Support = 40 |

| No. | Facility/ Centre Funder | Institution(s) | Established | Director | Coverage | Core Team | Studies |
|---|---|---|---|---|---|---|---|
| 5 | UCD Clinical Research Centre (UCD CRC)<br>HEA investment for the initial three years, Now UCD School of Medicine & Leveraged Funding | UCD, Mater Misericordiae and SVUH,<br>National Maternity Hospital & Ireland East Hospital Group | 2006 | Professor Peter Doran | Dublin/ Leinster and other national tertiary referrals | 18 Core<br>22 Project Specific | 225 |
| 6 | Children's Clinical Research Unit, National Children's Research Centre (NCRC)<br>Children's Medical Research Foundation (CMRF) | OLCHC (Children's Health Ireland from January 2019) | NCRC is over 50 years but the Children's Clinical Research Unit (CCRU) was established in 2010 | Professor Colm O'Donnell | Our Lady's Children's Hospital, Crumlin, with specific studies also supported by NCRC staff at Temple Street Children's University Hospital, Tallaght University Hospital, University Hospital Limerick and University College Hospital Galway. Centralised clinical research support service is available to all paediatric centres. Per the national paediatric model of care, the majority of quaternary and tertiary paediatric healthcare services are delivered by OLCHC and TSCUH (Children's Hospital Group). | 26 | 131<br>OLCHC: 110 (46 Haematology/ Oncology Trials Unit)<br>TSCUH: 6<br>TUH: 6<br>UCHG: 1<br>UHL: 8 |

| No. | Facility/ Centre Funder | Institution(s) | Established | Director | Coverage | Core Team | Studies |
|---|---|---|---|---|---|---|---|
| 7 | Health Research Institute Clinical Research Support Unit Limerick (HRI CRSU)<br>UHL and UL | ULH and UL | 2014 | Professor Rachel Msetfi | Mid-West region of Ireland with a population of just under 400,000 | 8 | Major support = 5<br>Minor support = 3 |
| 8 | Wellcome Trust-Wolfson Clinical Research Facility (NICRF)<br>Wellcome Trust and Wolfson Foundation | QUB, The Belfast Health and Social Care Trust, Ulster University and The Northern Ireland Health and Social Care Research and Development division | 2013 | Professor Judy Bradley | Northern Ireland | 9 F.T.E.<br>(10 Staff) | 25 studies in set-up/ approved and 47 studies Active/ Completed |

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