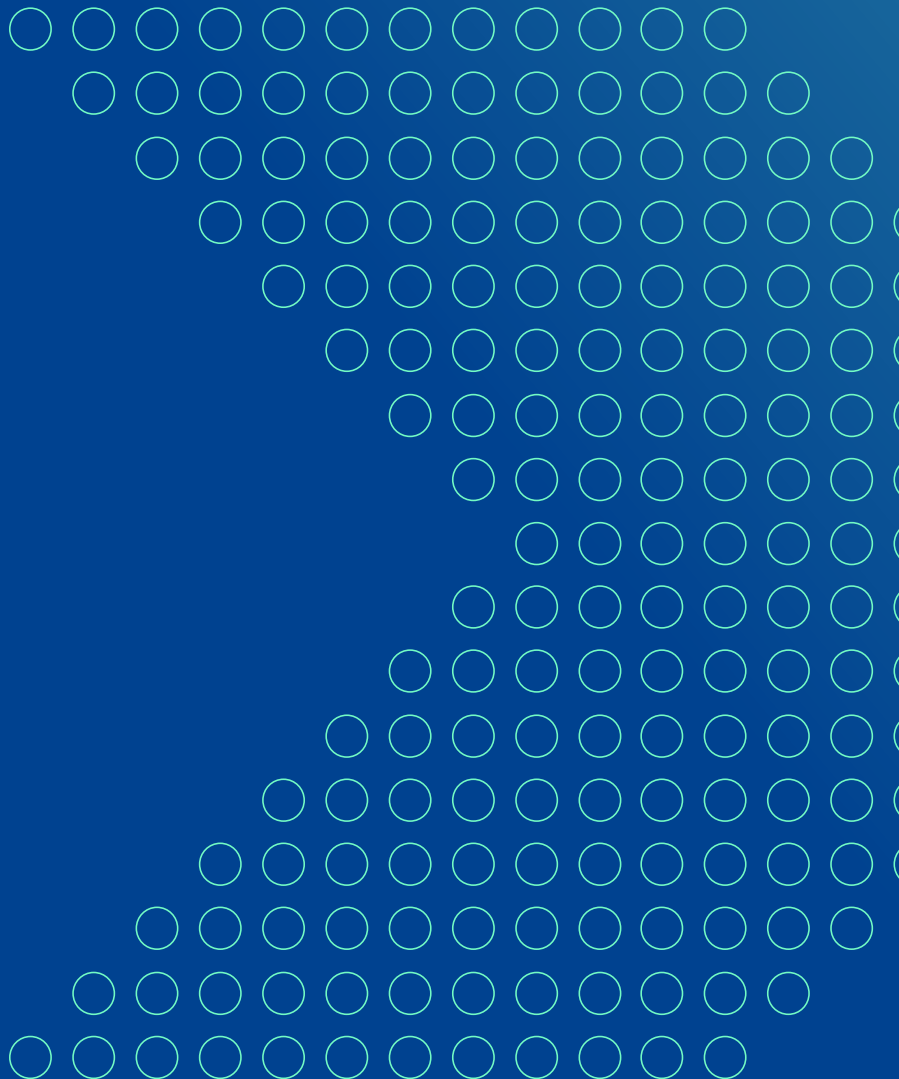


# Harnessing primary care data for clinical research and trial recruitment

Thursday 25<sup>th</sup> January 2024



## Interviewees

- > **Prof. Philip Evans**, Professor of Primary Care Research, University of Exeter Medical School and Deputy Medical Director NIHR Clinical Research Network (CRN)
- > **Hilary Fanning**, Director of Research Development and Innovation, University Hospitals Birmingham NHS Foundation Trust
- > **Dr. Alison Knight**, Data and AI Regulation/Law National Expert - Privacy Advisor Health Research Authority (HRA)
- > **Emma Lowe**, Head of Clinical Research Delivery, Department of Health and Social Care
- > **Prof. Martin Marshall CBE**, Chair of the Nuffield Trust
- > **Alex McLaughlin**, Deputy Director of Innovation and Growth, Office for Life Sciences
- > **Dr. Janet Messer**, Executive Director of Approvals, Health Research Authority (HRA)
- > **Dr. Simon Royal**, National Specialty Lead for Primary Care, National Institute for Health and Care Research (NIHR)
- > **Dr. Janet Valentine**, Executive Director of Innovation & Research, Association of British Pharmaceutical Industries (ABPI)
- > **Gemma Warren**, Data and AI Policy Manager, Health Research Authority (HRA)
- > **Dr. Tim Williams**, Head of Interventional Research, Clinical Practice Research Datalink (CPRD), Medicines and Healthcare products Regulatory Agency (MHRA)

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## Foreword

Healthcare research is essential for the development of life-saving innovations and it is self-evident that improvements in the quality of care can have huge benefits for patients. Unfortunately, not all parts of the healthcare system participate in research equitably. A substantial majority of it is carried out within secondary care, with historically less engagement with primary care.

Progress has been made in recent years, however, with 44 per cent of all GP practices in England participating in some sort of research in 2022/23. However, as noted in the Government's response to the 2023 Lord O'Shaughnessy review into commercial clinical trials, "there is strong potential for an increase in this research activity".

At a personal level, participating in clinical research makes me a better frontline GP. In addition to the intellectual stimulus, it exposes me to the latest ideas and evidence that support my clinical decision-making, keeping me up to date by constantly challenging my approaches to the delivery of high-quality care to our practice patients and their carers.

The UK NHS holds the most comprehensive longitudinal patient data anywhere on the planet and general practice Electronic Health records (EHR) are particularly impressive – many practices, including my own, hold data going back to the 1980s. This means that we have a remarkable resource at our disposal for research; using this data to tackle the growing challenges faced by NHS is imperative. Patients understand that medical research is essential for the continuous improvement of clinical practice, and they are keen to 'give something back' to the NHS by participating in research, yet overall primary care research recruitment figures continue to be disappointing.

There is no doubt that if we can provide concrete assurances about data protection, confidentiality, and security to the data controllers – GPs – then they in turn will be much more likely to engage actively and encourage their patients to participate in high-quality medical research. If we can utilise systems that make it straightforward to engage, then GPs and their teams are even more likely to step forward. Additionally, we need to ensure that research is everybody's business within primary care and not just the doctors.

In my own practice in the Midlands, we use our wider healthcare team, including a range of nursing and other clinical colleagues, in trial work. This helps with capacity issues and provides fantastic professional development opportunities for all. We engage with our research network actively and make use of text messaging services to directly communicate with patients about trials and help recruit them.

We all need to find innovative ways to overcome the challenges in primary care research and harness the data within GP EHRs to support research and clinical trial activity. This report brings together new research findings and provides constructive, pragmatic recommendations for improvement. Taken together these recommendations suggest a way to accelerate the pace of change and improve health and care.

**Professor Dame Helen Stokes-Lampard, Professor of GP Education, Birmingham Medical School, University of Birmingham**

## Executive Summary

The UK's health and care system produces a vast amount of data that can support research and deliver improvements in the quality of care patients receive. Primary care data are of particular importance due to their quality, richness, and longitudinal nature. It can serve to identify patients eligible for recruitment into clinical trials, be used to enrich other sources of data to carry out clinical research or be used to generate real-world evidence. Primary care, and the data it holds, must form an essential part of the post-pandemic rebuild of the UK's clinical research sector.

However, primary care lags far behind secondary care in its clinical research activity. GPs are under huge pressure to deliver care for patients and have limited time to engage in research. GPs lack incentives to undertake research, and there is less investment in infrastructure and capacity which has led to a less prevalent research culture in primary care. As a consequence, the vast majority of patients using primary care do not find themselves offered opportunities to participate in research.

As novel research for this paper demonstrates, there is a significant appetite among clinicians and patients to take part in research at the primary care interface. Most primary care health practitioners want to do more and feel that it would enhance their job satisfaction. Patients, too, would like more opportunities to take part in research. Making this happen requires clarity about the barriers that exist and precision about the changes needed to address them.

Research is impeded when GPs and other healthcare practitioners lack the tools to identify and recruit the right patients for trials, and often due to lack of time or resources, to directly engage with patients about research. There is wariness about the use of data and GPs' obligations as data controllers, as well as concern about the suitability of commercial research in a primary care setting. However, as the survey shows, even with these challenges the desire to do better is strong.

This paper makes six specific recommendations for addressing the barriers to primary care research:

**Recommendation 1:** The Royal College of General Practitioners, the Royal College of Nursing, the General Medical Council, the Nursing and Midwifery Council, the National Institute for Health and Care Research, NHS England and the Health Research Authority should provide clear guidance about how health and social care professionals should be best utilised within the primary care team to facilitate and support primary care research.

**Recommendation 2:** The National Institute for Health and Care Research's new Research Delivery Network should provide funding to train a wide range and number of primary healthcare practitioners in its upcoming Workforce Plan for Research Staff, with dedicated funding to support this.

**Recommendation 3:** The Department of Health and Social Care and NHS England should promote and facilitate the resourcing of primary care to take part in commercial trials so that primary care is reimbursed for the cost of undertaking research.

**Recommendation 4:** The Royal College of General Practitioners, the National Institute for Health and Care Research and the NHS England-funded Primary Care Networks should encourage the use of platforms embedded in primary care which facilitate the recruitment of diverse patients into clinical trials using data held within Electronic Health Records.

**Recommendation 5:** The Health Research Authority must ensure that primary care is appropriately represented in the development of their future guidance on ‘identifying and contacting people about research’, which will seek to reduce current variation in the interpretation of the law.

**Recommendation 6:** The Royal College of General Practitioners, the National Institute for Health and Care Research and the NHS England-funded Primary Care Networks should develop guidance that encourages GP practices to use texting services to engage directly with patients about taking part in research. Further information about suitable trials that patients are eligible for should be provided directly to them to increase engagement and participation.

## Introduction

The NHS recognises that “the value of research in transforming health and care is significant”.<sup>1</sup> It is the backbone of “all advances in health and care and is the basis for evidence-based practice” and is key to understanding which clinical interventions work and which ones do not.<sup>2</sup> The UK has a strong history of leading clinical research and demonstrated its strengths during the pandemic with the RECOVERY, PANORAMIC, COVID-19 vaccine and other trials. This is partly due to the favourable institutional landscape for clinical research, with leading universities and medical research charities, as well as organisations like UK Biobank and Genomics England, and unique data assets such as the Clinical Practice Research Datalink (CPRD), the largest research database in the UK, or cohort studies like Our Future Health and SAIL Databank.<sup>3</sup>

Despite this strong history, there has been growing concern in recent years about the state of clinical research in the NHS, especially for commercial clinical trials activity.<sup>4</sup> While the UK ranked fourth in the number of phase 1 trials initiated in 2021, it fell to tenth when looking at phase 3 commercial trials.<sup>5</sup> The UK’s performance can be partly explained by the fact that it does not yet make the best use of the data held within the NHS. It is not yet systematically leveraging the multiple electronic health record (EHR) systems and registries that exist to proactively identify, stratify, and approach trial candidates without them having already consented to being approached, or to generate data for regulatory submissions.

This is particularly true in primary care: despite 90 per cent of all NHS health contacts occurring in this environment, it only delivers around 10 per cent of all clinical trial activity.<sup>6</sup> As highlighted by interviews carried out for this paper, primary care professionals wanting to participate in research face significant capacity and administrative challenges. If we are to expand the range and reach of clinical research, it is imperative to find ways of enabling primary care professionals to play a role and participate in research more easily. Platforms such as OpenSAFELY, which allow for the analysis of EHR data,<sup>7</sup> and the work of health IT system providers, such as EMIS, have created opportunities to deliver improvements which embed clinical research into day-to-day clinical workflow.

This paper explores the value of primary care data for research and clinical trials before uncovering the challenges of engaging with research and clinical trials in primary care. Finally, it outlines ways of facilitating research and clinical trial activity in primary care. The paper also presents novel data from surveys from 1,869 patients, and 127 healthcare

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<sup>1</sup> NHS England, ‘Maximising the Benefits of Research: Guidance for Integrated Care Systems’, Webpage, NHS England, 13 March 2023.

<sup>2</sup> Ibid.

<sup>3</sup> Our Future Health, ‘About Us’, Webpage, Our Future Health, 2023; SAIL Databank, ‘Home’, Webpage, SAIL Databank, 2021.

<sup>4</sup> Lord James O’Shaughnessy, *Commercial Clinical Trials in the UK: The Lord O’Shaughnessy Review* (Department for Science Innovation and Technology, Department of Health and Social Care and Office for Life Sciences, 2023); Association of British Pharmaceutical Industry, ‘Number of Industry Clinical Trials Initiated per Year, by Country (2012-2021)’, Webpage, ABPI, 20 September 2023; Association of British Pharmaceutical Industry, ‘Average Number of Participants Treated per Industry Clinical Trial, by Country, by Phase (2018-2020)’, Webpage, ABPI, 20 September 2023.

<sup>5</sup> Lord James O’Shaughnessy, *Commercial Clinical Trials in the UK: The Lord O’Shaughnessy Review*.

<sup>6</sup> Health and Social Care Committee, *The Future of General Practice*, HC 113 (House of Commons, 2022); Lord James O’Shaughnessy, *Commercial Clinical Trials in the UK: The Lord O’Shaughnessy Review*.

<sup>7</sup> OpenSAFELY, ‘About OpenSAFELY’, Webpage, OpenSAFELY, 2023.

professionals who are EMIS users, about attitudes to clinical research engagement, participation, and delivery.<sup>8</sup> A research roundtable was also held to discuss some of the key findings and recommendations made in the paper. A summary of the discussion has been added as an addendum to the paper and key pieces of feedback directly from stakeholders have been integrated into the paper.

## Importance of primary care data for research

Most contacts between the patient and the health and care system “originate and end in primary care”.<sup>9</sup> These interactions have been recorded electronically in EHRs for several decades – by 1996, 96 per cent of GP practices used an EHR.<sup>10</sup> This has led to the creation of a repository of the “longitudinal medical history of 98 per cent of the UK population who uses the NHS” which “provides an excellent research tool”.<sup>11</sup>

*“Without research, medicine cannot move forward” –  
comment from a surveyed patient.*

The primary care record represents the “full spectrum of disease”<sup>12</sup> and contains “information encompassing symptoms, diagnoses, prescribing, laboratory tests and data from hospital visits and admissions”.<sup>13</sup> This has immense value for research, which in turn can have a direct benefit to the quality of care received by patients. Primary care data can be used for several research purposes: from identifying and recruiting patients for clinical trials to enriching secondary care research by linking data together or providing real-world evidence.

### 1. Identifying patients for clinical research

The richness and continuity of the primary care records mean that it can be easier to identify patients for clinical research than it would be using other methods. During an interview for this paper, Prof. Philip Evans, Professor of Primary Care Research at the University of Exeter Medical School, aptly described this by saying that “the vast majority of candidates for trials can be identified from their primary healthcare records”. Furthermore, as other interviewees for this paper highlighted, primary care data are particularly useful for recruiting patients with certain types of long-term conditions, such as diabetes or asthma, as they are managed within the primary care setting.

### 2. Enriching secondary care data

Data collected within secondary care are more episodic than longitudinal as they only capture the interactions that happen within a hospital. Secondary care data also rarely

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<sup>8</sup> Patient survey: patients were contacted by EMIS using a newsletter and 1,869 patients responded to the survey. Healthcare practitioner survey: healthcare practitioners who use EMIS were sent a survey which got 127 responses. The survey was carried out from November-December 2023.

<sup>9</sup> Richard Hobbs, ‘Is Primary Care Research Important and Relevant to GPs?’, *The British Journal of General Practice* 69, no. 686 (30 August 2019): 424–25.

<sup>10</sup> Stephen H Bradley, Neil R Lawrence, and Paul Carder, ‘Using Primary Care Data for Health Research in England – an Overview’, *Future Healthcare Journal* 5, no. 3 (October 2018): 207–12.

<sup>11</sup> Matthew R Sydes et al., ‘Realising the Full Potential of Data-Enabled Trials in the UK: A Call for Action’, *BMJ Open* 11, no. 6 (June 2021): 2.

<sup>12</sup> Hobbs, ‘Is Primary Care Research Important and Relevant to GPs?’

<sup>13</sup> Sydes et al., ‘Realising the Full Potential of Data-Enabled Trials in the UK’, 2.



contain the long-term outcomes of an operation or treatment, which would generally be captured within primary care. A study has highlighted that there “is considerable overlap between the data that researchers need to assess the impact of interventions on patients and what is already routinely collected in patient’s health records.”<sup>14</sup> This is why data contained within primary care can be complementary to data held by hospitals, a point made by Emma Lowe, Head of Clinical Research Delivery at the Department of Health and Social Care.

### 3. Real-world evidence

According to Hilary Fanning, Director of Research Development and Innovation at University Hospitals Birmingham NHS Foundation Trust, “data collected within primary care are key to understanding the patient journey and outcomes which generate real-world evidence”. Real-world evidence – defined as “evidence obtained outside the context of a randomised controlled trial”<sup>15</sup> – is essential to understanding how patients react to a treatment in everyday life. It can have beneficial impacts on the robustness and accuracy of research as it “enables a more robust critical assessment of technologies and can validate whether the study population and clinical context of a randomised clinical trial (RCT) are reflective of clinical practice”.<sup>16</sup> It can also help with the production of high-quality data for regulatory submission as highlighted by roundtable attendees.

A study from 2020 has shown that when real-world evidence found within primary care record is used for submissions to the National Institute for Health and Care Excellence (NICE), evidence review groups and the appraisal committees are generally more favourable to the applicant.<sup>17</sup> The study recommends that primary care data should be “given greater consideration when planning health economics and outcomes research (HEOR) strategies to support market access in England”.<sup>18</sup>

## Challenges in primary care research

Research within primary care faces a variety of challenges and this section will focus on four of the most significant:

1. The lack of capacity to engage with and prioritise research. GPs face growing pressures and workload which makes it difficult for them to engage in research.
2. Awareness of ongoing clinical studies cannot be assumed without access to appropriate tools. This task can be perceived as arduous and time-consuming.
3. Recruiting appropriate patients into clinical research can be difficult and it is known to be one of the most challenging aspects of running a study.<sup>19</sup>

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<sup>14</sup> Ibid., 1.

<sup>15</sup> Thomas P. Leahy, Sreeram Ramagopalan, and Cormac Sammon, ‘The Use of UK Primary Care Databases in Health Technology Assessments Carried out by the National Institute for Health and Care Excellence (NICE)’, *BMC Health Services Research* 20, no. 1 (22 July 2020): 675.

<sup>16</sup> Ibid.

<sup>17</sup> Ibid.

<sup>18</sup> Ibid.

<sup>19</sup> Amanda Blatch-Jones et al., ‘Using Digital Tools in the Recruitment and Retention in Randomised Controlled Trials: Survey of UK Clinical Trial Units and a Qualitative Study’, *Trials* 21, no. 1 (3 April 2020): 304; J C Crocker et al., ‘Recruitment and Retention of Participants in UK Surgical Trials: Survey of Key Issues Reported by Trial Staff’, *BJS Open* 4, no. 6 (1 December 2020): 1238–45; Daisy Elliott et al., ‘Understanding and Improving Recruitment to Randomised Controlled Trials: Qualitative Research Approaches’, *European Urology* 72, no. 5 (1 November 2017): 789–98; Rashmi Ashish Kadam et al., ‘Challenges in Recruitment and Retention of Clinical Trial Subjects’, *Perspectives in Clinical Research* 7, no. 3 (2016): 137–43.

4. Directly engaging with patients about clinical research including trials is not always straightforward as there are legal implications in doing so.<sup>20</sup>

## 1. Lack of GP engagement in research

GPs can play an active role in research by simply helping to recruit patients for studies carried out by research teams or by actively recruiting and running studies themselves. According to the National Institute for Health and Care Research (NIHR), 44 per cent of GP practices in England “recruited one or more participants into NIHR CRN Portfolio studies in 2022/23”<sup>21</sup>, which is “slightly below the annual ambition of 45 per cent.”<sup>22</sup> In the same 2022/23 period, 18 per cent of commercial research participants came from primary care.<sup>23</sup> These levels of activity are encouraging, but more can be done to support GPs to further engage with research.

Workload pressures undoubtedly have an impact on the ability of primary care staff to carry out research, which was unanimously highlighted as a major problem by interviewees. The Royal College of General Practitioners has said their workload is “unmanageable” and “workforce pressures are fuelling an exodus of fully qualified GPs”.<sup>24</sup> A Health Foundation report from 2023, found that “UK GPs report higher levels of emotional distress and bigger rises in workload than GPs in nearly all other countries”.<sup>25</sup> This is also corroborated by the findings from the healthcare practitioner survey carried out for this paper as shown in Figure 1.

**Figure 1: Top six most cited barriers impeding primary care practitioners from contributing to clinical research**



Source: Infographic based on data from the healthcare practitioner survey using the top six most selected options to the multiple-choice question ‘What do you think are the biggest barriers to you contributing to clinical research?’

<sup>20</sup> Lord James O’Shaughnessy, *Commercial Clinical Trials in the UK: The Lord O’Shaughnessy Review*.

<sup>21</sup> The NIHR Clinical Research Network (CRN) transitioned into the NIHR Research Delivery Network (RDN) in 2024.

<sup>22</sup> National Institute for Health and Care Research, ‘NIHR Clinical Research Network High Level Objectives Outturn Report 2022/23’, Webpage, NIHR, August 2023.

<sup>23</sup> National Institute for Health and Care Research, ‘Annual Statistics’, Webpage, NIHR, 3 August 2023.

<sup>24</sup> Royal College of General Practitioners, ‘A Quarter of GP Practices Could Close Because of Workload Pressures, Warns Royal College of GPs’, Webpage, RCGP, 10 March 2023.

<sup>25</sup> Jake Beech et al., *Stressed and Overworked - What the Commonwealth Fund’s 2022 International Health Policy Survey of Primary Care Physicians in 10 Countries Means for the UK* (The Health Foundation, 2023).

Nonetheless, several interviewees highlighted that other factors might be at play; for example, there is a less research-focused culture in primary care compared to secondary care. Prof. Martin Marshall, Chair of the Nuffield Trust, said that “general practice is culturally less geared towards research than the acute sector is”, adding that clinicians who go into general practice are often more focused on delivering frontline care rather than research.

As highlighted by the survey results in Figure 1, primary care staff might lack the necessary knowledge and training to take part in research and might not be aware of the benefits of doing so. One explanation for this is that “doctors and nurses in primary care are not embedded within the clinical trial apparatus”, as identified by Dr. Tim Williams, Head of Interventional Research at the Clinical Practice Research Datalink (CPRD). Prof. Philip Evans also highlighted that primary care is a “neglected or underserved area of healthcare research”.

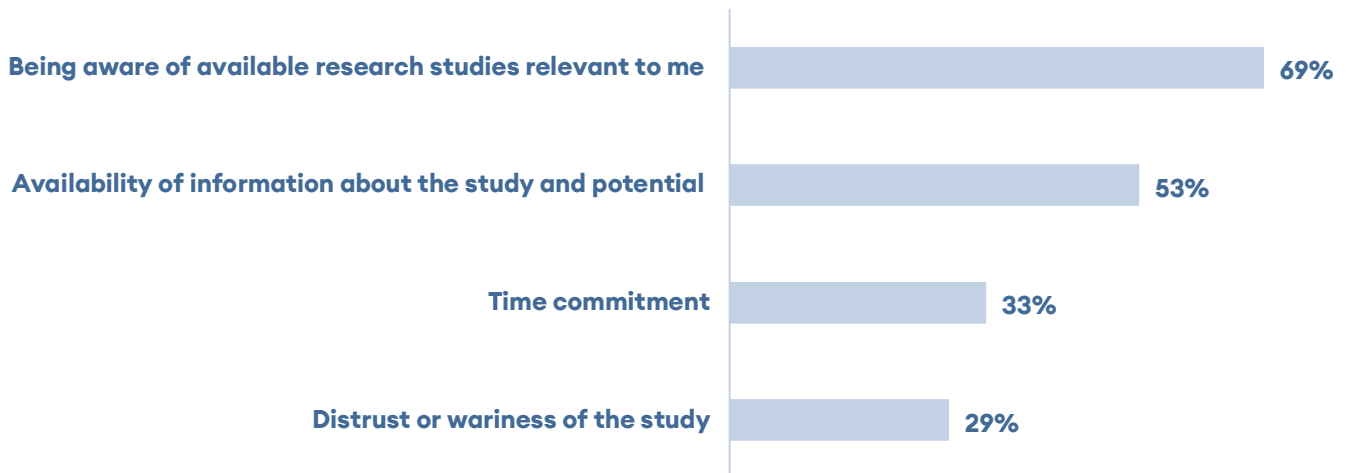
The varying sizes of primary care practices and the multiplicity of practices can also make it difficult for GPs to participate in research or for study sponsors to want to engage. Prof. Philip Evans stated that the scale of GP practices can make it more complex for them to have the proper infrastructure in place to engage in research. Scale will be a key factor for pharmaceutical companies to further engage primary care in clinical trial recruitment according to Dr. Janet Messer, Executive Director of Approvals at the Health Research Authority (HRA): “the fragmentation of the GP landscape and the multitude of practices means that many pharmaceutical companies do not want to engage with primary care for trial recruitment as they do not want to deal individually with 6,000 practices.”

## **2. Lack of awareness of available clinical studies**

The first step to recruiting patients into a clinical study is having the knowledge that the study exists and is ongoing. Health and care professionals have to keep abreast of ongoing studies in their areas to suggest these to their patients, which can be time-consuming. Lack of awareness of clinical studies suitable for their specific patients was the second most cited barrier impeding GPs from participating in research, as shown in Figure 1.

The lack of awareness of ongoing studies to take part in can also be found in patients. As shown in Figure 2, 69 per cent of patients surveyed for this paper stated that the biggest barrier to taking part in clinical research was being aware of available research studies relevant to them and 53 per cent of them mentioned that the availability of information about the study and potential benefits was also a key barrier.

**Figure 2: Barriers to patients taking part in clinical research**



Source: Based on data from the patient survey undertaken for this paper, using the responses to the question 'what do you feel are the biggest barriers in taking part in clinical research?'

Increasing awareness of clinical studies is key to recruitment.<sup>26</sup> Addressing this challenge will mean making sure that both patients and primary care practitioners have a better understanding of relevant ongoing studies in their area. The NIHR's Be Part of Research service provides a searchable database of studies taking place across the country with over 370,000 volunteers who have registered to be part of the service and find out about research taking place across the UK.<sup>27</sup>

### 3. Challenges in identifying and recruiting the right patients

According to the NIHR, 1,003,285 patients have been recruited into research studies, including clinical trials, in England in the year ending in April 2023.<sup>28</sup> Strong progress has been made in terms of trial recruitment. In December 2022, only 35 per cent of studies were recruiting to time and target, but by November 2023, it increased to 82 per cent.<sup>29</sup> Efforts should be geared towards maintaining this trend.

Under-recruitment of patients into clinical trials creates a "significant barrier to translating basic science discoveries into medical practice."<sup>30</sup> This has a direct knock-on impact on the treatment and quality of care that patients can receive. In the survey carried out for this

<sup>26</sup> Isla S Mackenzie et al., 'Promoting Public Awareness of Randomised Clinical Trials Using the Media: The "Get Randomised" Campaign', *British Journal of Clinical Pharmacology* 69, no. 2 (February 2010): 128–35; Nick Peel, 'Raising Awareness of Cancer Clinical Trials', Webpage, Cancer Research UK - Cancer News, 11 February 2015; Ida Darmawan et al., 'The Role of Social Media in Enhancing Clinical Trial Recruitment: Scoping Review', *Journal of Medical Internet Research* 22, no. 10 (26 October 2020): e22810.

<sup>27</sup> Department of Health and Social Care, *Full Government Response to the Lord O'Shaughnessy Review into Commercial Clinical Trials*, 2023.

<sup>28</sup> CRN North Thames and CRN North West London, 'CRN North Thames & CRN North West London Joint Research Specialty Leads Meeting' (National Institute for Healthcare Research, 12 October 2023).

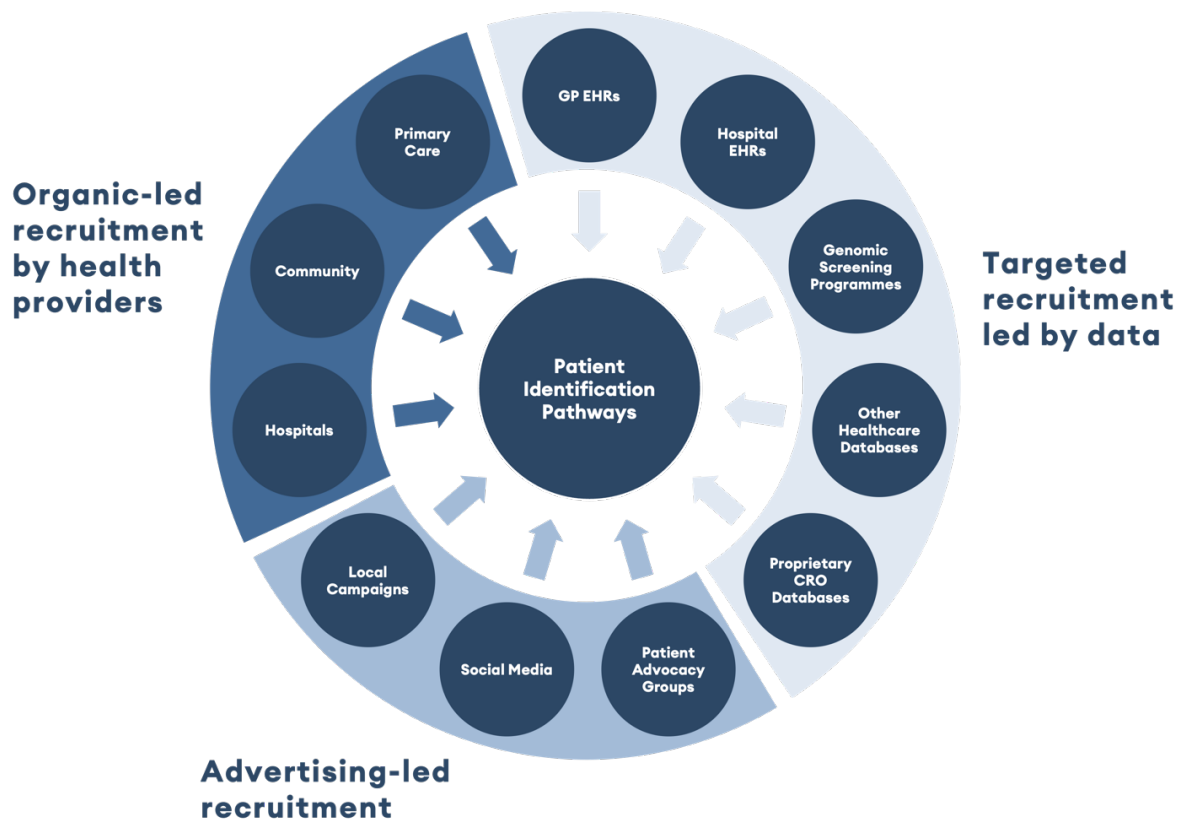
<sup>29</sup> Department of Health and Social Care, *Research Status Report*, 2023.

<sup>30</sup> Teresa Taft et al., 'Primary Care Perspectives on Implementation of Clinical Trial Recruitment', *Journal of Clinical and Translational Science* 4, no. 1 (February 2020): 61.

paper, results show that the ability to identify suitable patients for a research study was identified as a key barrier by 73 per cent of healthcare professionals.<sup>31</sup>

Identifying the right patients to take part in a study can be complex and there are many ways patients may be identified as eligible to take part in a research study (see Figure 3).

**Figure 3: Ways of approaching patients for research studies**



Source: Based on background research carried out by Newmarket Strategy.

Patients can be approached through direct interaction with a healthcare provider – that could be a GP mentioning to a patient that a study they might want to take part in is happening or a hospital-based oncology consultant suggesting a trial to a cancer patient. Approaching patients this way is not the most efficient as it relies on health and care professionals knowing about a study, remembering its inclusion and exclusion criteria, correctly identifying which patients may be suitable, and remembering to speak to the patients about the trial within the recruitment timeframe.

New and innovative methods to recruit clinical study participants are now being used, with some studies turning to social media to approach participants. This can offer advantages compared with traditional methods such as physician recommendation, TV, radio, and newspaper advertising<sup>32</sup> by lowering costs and increasing reach – particularly for diverse or

<sup>31</sup> 93 out of 127 patients scored the ability to identify patients as a barrier between 5-8 from a scale 1-8 with 1 being not a barrier at all and 8 being a strong barrier (4 is neutral).

<sup>32</sup> Darmawan et al., 'The Role of Social Media in Enhancing Clinical Trial Recruitment'.

hard-to-reach groups.<sup>33</sup> Nonetheless, Dr. Tim Williams stated these methods tend to be less precise than the use of primary care data.

Patients can also be identified and approached by using more targeted data-driven approaches. Clinical research organisations (CROs) are often commissioned by research sponsors to perform recruitment tasks, although this can be an expensive approach which also involves ceding control over much of the trial recruitment and management process.<sup>34</sup>

Even though the UK has the “best primary care data in the world”, as highlighted by Dr. Janet Valentine, Executive Director for innovation and Research Policy at the Association of the British Pharmaceutical Industry (ABPI), all interviewees for this paper agreed that the UK does not make the most of the value that lies within primary care data for clinical research. Dr. Tim Williams stated that “clinical trial protocols involve inclusion or exclusion variables that are time-dependent, for example, the timeframe from diagnoses, procedures or prescriptions”.<sup>35</sup> This means that identifying, approaching and recruiting patients can be complex and costly if primary care data are not used to clearly identify and target patients.

#### 4. Directly engaging with patients

Currently, the UK’s legal framework allows for patients to be contacted to be part of research if:

1. the contact is made by a member of that patient’s clinical care team, for example a nurse or GP; or
2. they have previously consented to be contacted to be part of research; or
3. the project sponsor seeks section 251 support from the HRA.<sup>36</sup>

However, it is not always clear to research sponsors what the best way to engage with patients is. This means, as the O’Shaughnessy Review highlights, that “we are not systematically using our proliferation of databases, registries, cohorts and EHRs to proactively identify, stratify and approach potential clinical trial candidates”.<sup>37</sup>

The survey of patients carried out for this paper confirmed this view: 69 per cent agreed that they would like the opportunity to take part in clinical research as a patient. However, only 14 per cent of surveyed patients had been offered the opportunity to take part in a clinical study by their GP Practice. One patient even commented that they “took part in COVID vaccine trials and found that it was a satisfying experience and would take part in other trials, if [they] knew about them”. Patients would like the ability to engage more with research and have

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<sup>33</sup> Elizabeth Mirekuwaa Darko, Manal Kleib, and Joanne Olson, ‘Social Media Use for Research Participant Recruitment: Integrative Literature Review’, *Journal of Medical Internet Research* 24, no. 8 (4 August 2022): e38015.

<sup>34</sup> Daniel A. Roberts, Hagop M. Kantarjian, and David P. Steensma, ‘Contract Research Organizations in Oncology Clinical Research: Challenges and Opportunities’, *Cancer* 122, no. 10 (2016): 1476–82.

<sup>35</sup> Sydes et al., ‘Realising the Full Potential of Data-Enabled Trials in the UK’, 5.

<sup>36</sup> Section 251 is a legal instrument within the NHS Act 2006 which enables the access data without consent thanks to the thorough review of the Health Research Authority’s Confidentiality Advisory Group (CAG).

<sup>37</sup> Lord James O’Shaughnessy, *Commercial Clinical Trials in the UK: The Lord O’Shaughnessy Review*.

greater access to information about ongoing studies and trials. An overwhelming majority of patients view clinical research as important.

*“I would be happy to participate in clinical trials as I believe they are an essential part of providing the best care for future generations” – comment from a surveyed patient.*

Following the O’Shaughnessy Review, the HRA has been tasked to clarify how patients could be directly contacted for research that would have a solid legal basis and be seen as best practice.<sup>38</sup> The HRA are currently finalising their report and guidance.

Once this is in place, utilising existing patient touch points, including digital platforms for direct patient care to facilitate patient engagement, could be considered to maximise opportunities for patients to get involved in clinical research.

## **5. Wariness around data protection and giving access to data**

In several interviews carried out for this paper, individuals mentioned that – as sole data controllers – GPs can be concerned about the legal ramifications of allowing access to data held within primary care for research purposes. Dr. Alison Knight, Data and AI Regulation/Law National Expert and Privacy Advisor at the HRA, stated that “GPs have very real concerns about the fact that they are sole controllers of data held within their practice”. This concern is exacerbated by the fact that “they do not feel like they have received enough training to understand how controllership works”. Prof. Philip Evans explained that “GPs do not have R&D departments or data protection officers (DPOs) in-house” and added that GPs often use DPOs within ICBs to get advice and they may be “risk averse.”

Survey results also seemed to support this stated wariness with several free text answers underlining concerns around data protection and giving access to data. One response highlighted that GPs can be “very wary of sharing our clinical data” with other organisations as they have sometimes found themselves “competing with them to recruit our patients to the same trials.”

## **Facilitating research and clinical trial activity in primary care**

Rebuilding the UK’s clinical research sector cannot be fully achieved without making the most of the assets and capabilities of the primary care sector. Primary care data “can have enormous benefits”<sup>39</sup> to research including the identification of patients for trials – this should be harnessed for the benefit of patients. GPs should be provided with the right level of assurance about how data are being accessed, what the consent process is and how the data will be used. GPs should also be encouraged to adopt solutions which have a positive impact on the engagement of primary care professionals in research, and policymakers should work

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<sup>38</sup> Department of Health and Social Care, *Full Government Response to the Lord O’Shaughnessy Review into Commercial Clinical Trials*.

<sup>39</sup> Fahmida Mannan et al., ‘Outputs and Growth of Primary Care Databases in the United Kingdom: Bibliometric Analysis’, *BMJ Health & Care Informatics* 24, no. 3 (1 July 2017).

to improve the awareness of trials amongst patients and GPs so that they can more easily engage with research.

## 1. Improving the engagement of primary care professionals in research

GPs are under pressure to care for their patients and on average only have seven minutes per patient consultation.<sup>40</sup> It is therefore vital to ensure that research can be embedded in their workflow and made easy for them to engage with, as was unanimously highlighted by interviewees. It is also important for GPs to understand that there are varying ways for them to engage in research and that not all research activities need to be necessarily delivered by them.

### Having the right tools

Dr. Simon Royal, National Specialty Lead for Primary Care at the NIHR, expressed in an interview for this paper that it is essential to make recruitment as easy as possible. This means that GPs need to have access to the right tools to do so – including “the right IT systems” as highlighted by Alex McLaughlin, Deputy Director of Innovation and Growth at Office for Life Sciences. One study has shown that when an electronic flag is “triggered at the point of consultation”, recruitment into research trials has “approximately nine-fold” increase compared “to prospective research [...] with searching for symptom codes and study mailouts.”<sup>41</sup>

### Case study Recruit from EMIS

EMIS, the leading clinical technology supplier in the UK for primary care, has developed an integrated solution to simplify clinical trial recruitment via their GP users across England.

Embedded as a free platform within the EMIS Web clinical system, Recruit automates searches against EHR data to surface patients who may meet eligibility criteria for clinical trials recruiting in a local area. Practices can enable this platform, browse recruiting studies, and invite patients to be involved, all from within the same platform they use daily to manage patient care.

Supporting primary care providers to tap into their healthcare data in this way is enabling a more targeted approach to trial recruitment, speeding up lengthy recruitment processes and making clinical research opportunities more accessible to citizens throughout the country. In doing so, studies can also benefit from a more diverse range of participants, supporting research that is representative of, and beneficial to, the entire population.

<sup>40</sup> The King's Fund, 'Understanding Pressures in General Practice', Webpage, The King's Fund, 5 May 2016.

<sup>41</sup> Gillian Doe et al., 'Comparing Research Recruitment Strategies to Prospectively Identify Patients Presenting with Breathlessness in Primary Care', *Npj Primary Care Respiratory Medicine* 32, no. 1 (9 November 2022): 3.



The Recruit solution from EMIS also encompasses recommendation 22 of the 2023 Lord O’Shaughnessy review into commercial clinical trials, which advocates for incentives to be introduced for GPs. With built-in remuneration, practices using Recruit receive automatic payments for all eligible patients they invite that consent to share their contact details with the research organisation.

Solutions like Recruit show how digital solutions can help to embed clinical research into existing ways of working within primary care, without adding unnecessary burden to an already stretched workforce. Add to this the ability to scale this solution using cloud technology across federated organisations such as Primary Care Networks (PCNs) and Integrated Care Systems (ICSs), and there lies a huge opportunity to put clinical research at the heart of patient care across the NHS.

In the survey carried out for this paper, 68 per cent of surveyed healthcare practitioners stated that they are more likely to engage in research if it is simply available in their clinical system. The case study above provides one example of how technology could be used to simplify trial recruitment within primary care.

These types of tools, which can be embedded within the clinical workflow, should be encouraged to facilitate engagement in research. Participation in research would also have a positive impact on GP’s working experience: 56 per cent of surveyed healthcare practitioners agreed that they would have an increased job satisfaction if they were able to participate in clinical research and only 13 per cent think that they would not.

### **Using all qualified staff in primary care**

For GPs to be able to play a meaningful role in research, given the reality of the workload pressures, other members of primary care staff must be trained to get involved in research. Emma Lowe highlighted “that there is no reason why you couldn’t have more chief investigators and principal investigators in a research study that are nurses”. This would also provide avenues for professional development.

Allied health professionals as well as practice managers could potentially play a role in discussing trials recommended by GPs, ensuring that patients have access to necessary information and support while maintaining the crucial GP-patient relationship. Involving other practice staff, like research nurses, can distribute the workload more effectively, further minimising the burden on GPs. This approach allows GPs to focus on their clinical responsibilities while facilitating research participation through the trusted primary care network. Roundtable attendees highlighted that some local areas have made great progress with clarifying what role different healthcare professionals can play in research by creating

clear job descriptions and engaging with healthcare professionals to explain the multiplicity of ways in which they can engage in research (see Addendum).

**Recommendation 1:** The Royal College of General Practitioners, the Royal College of Nursing, the General Medical Council, the Nursing and Midwifery Council, the National Institute for Health and Care Research, NHS England and the Health Research Authority should provide clear guidance about how health and social care professionals should be best utilised within the primary care team to facilitate and support primary care research.

### **Improving training**

The survey findings presented in Figure 1 demonstrate the importance of the need for access to further training to facilitate participation in research in primary care. The Department for Health and Social Care recently announced the new NIHR Research Delivery Network (RDN), intended to focus on the “successful delivery of health and social care research”.<sup>42</sup> Training for primary care practitioners should be regarded as a core part of the success of this new delivery network. The RDN will be publishing a workforce plan for research staff as highlighted in the research roundtable carried out for this paper (see Addendum).

**Recommendation 2:** The National Institute for Health and Care Research’s new Research Delivery Network should provide funding to train a wide range and number of primary healthcare practitioners in its upcoming Workforce Plan for Research Staff, with dedicated funding to support this.

### **Collaborating across networks**

Larger practice groups tend to be more strategic and organised in their research efforts compared to small single GP practices. Scaling up research efforts at a Primary Care Network, Integrated Care System level, or at the level of the NIHR Research Delivery Network can help smaller practices to further engage with research. Interviews for this paper highlighted the importance of primary care practices collaborating with other organisations to increase the scale of the research they can undertake.

EHR providers in primary care have a crucial role to play in helping to provide scale. EMIS and TPP have collaborated with the University of Oxford to create OpenSAFELY, which “provides secure access to full de-identified EHR records held by TPP and EMIS (>99% of patients in England, combined) and enables consistent, federated analysis across the two.”<sup>43</sup>

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<sup>42</sup> National Institute for Health and Care Research, ‘Department for Health and Social Care Announces New NIHR Research Delivery Network’, Webpage, 14 November 2023.

<sup>43</sup> Lara Edwards et al., ‘UK Research Data Resources Based on Primary Care Electronic Health Records: Review and Summary for Potential Users’, *BJGP Open* 7, no. 3 (1 September 2023).

### Offsetting the cost of research

The cost of undertaking research in primary care is not negligible. GPs need to ensure that their practice is set up in the right way to be able to engage with research and that they can recruit qualified staff to support them in undertaking research. Dr. Simon Royal noted the importance of making sure that GPs are adequately compensated for their efforts and the cost of research offset. Roundtable attendees reflected on the need for greater homogenisation in the costing of studies between primary and secondary care.

Financial support is key to encouraging research participation according to several interviewees for this paper. Survey responses highlighted that the current way of funding primary care research does not work as it does not cover a lot of the infrastructure investment GP practices have to make which means that research is “currently prohibitive especially to a lot of smaller surgeries” as highlighted by a GP survey respondent. The O’Shaughnessy review recommended that “financial incentives should be introduced for GPs to take part in commercial trials”<sup>44</sup> to increase activity.

**Recommendation 3:** The Department of Health and Social Care and NHS England should promote and facilitate the resourcing of primary care to take part in commercial trials so that primary care is reimbursed for the cost of undertaking research.

## 2. Improving the awareness of research opportunities and identification of patients

As highlighted by Alex McLaughlin, “general practice should be fundamental to the recruitment of patients into clinical trials.” 81 per cent of surveyed GPs think that primary care has a significant role to play in furthering clinical research for patient benefit. However, as previous sections explain they face challenges in terms of the awareness of trials and their ability to identify the right patients.

Finding ways to facilitate awareness and identification of patients will be key to increasing engagement in research. Tools like Recruit from EMIS allow GPs to find out about studies happening within their local area so they can make an informed decision about whether to participate or not. It enables a targeted approach to patient recruitment as it can produce a list of eligible patients using data stored in the EHR, but only once the GP has consented to be part of the study.

Emma Lowe mentioned in her interview that using primary care data for clinical trial recruitment can also have a positive impact on the diversity of patients in trials. In the NHS Galleri Trial, patients were approached using the NHS DigiTrials service and then gave their consent for the primary care data to be accessed by the study team. The addition of this real-world data was proven to be “a beneficial way of including data from more underrepresented

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<sup>44</sup> Lord James O’Shaughnessy, *Commercial Clinical Trials in the UK: The Lord O’Shaughnessy Review*.

populations in the drug approval processes”.<sup>45</sup> There are several ways in which primary care data can be used to respond to data diversity challenges.

**Recommendation 4:** The Royal College of General Practitioners, the National Institute for Health and Care Research and the NHS England funded Primary Care Networks should encourage the use of platforms embedded in primary care which facilitate the recruitment of diverse patients into clinical trials using data held within Electronic Health Records.

### 3. Increasing patient engagement

Patients are acutely aware of the importance of conducting clinical research in the NHS. 87 per cent of surveyed patients agreed that it is important for the NHS to conduct clinical research, but they lacked awareness of how to participate.

*“Studies should be better advertised by GPs” – comment from a surveyed patient.*

Some organisations have found an effective way to engage with patients by harnessing the GP-patient relationship, which is at the core of primary care<sup>46</sup> and could play a pivotal role in clinical research. Patients trust their GPs to guide them in matters of health and care. Interviews carried out for this paper highlight the importance of GP involvement in the recruitment of patients into clinical trials. This was corroborated by the findings of the survey as approximately 62 per cent of surveyed patients agreed or strongly agreed that they would be more likely to take part in research if the research had been suggested by their GP (see Figure 4).<sup>47</sup>

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<sup>45</sup> Abigail Beaney, ‘Real-World Data Bolsters Underrepresentation in UK Clinical Trials’, *Clinical Trials Arena* (blog), 7 November 2023.

<sup>46</sup> Nick Bostock, ‘GP Relationship with Patients “as Important as a Scalpel to a Surgeon”, Says RCGP Chair’, Webpage, GPonline, 11 February 2021.

<sup>47</sup> 605 patients said that they agreed, and 550 patients said that they strongly agree that they would be more likely to take part in research if it was suggested by their GP out of 1869 surveyed patients.

**Figure 4: Patient survey results to the question: How much do you agree with the following statements**

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
I think it is important for clinical research to be conducted in the NHS	5.8%	1.1%	5.9%	18.1%	69.1%
I think clinical research impacts my care	7.3%	6.6%	16%	27.7%	42.4%
I would like to have the opportunity to take part in clinical research as a patient	6%	4%	21.3%	29.3%	39.3%
I am more likely to take part in research if it has been suggested by my GP	6.7%	5.2%	26.3%	32.4%	29.4%

Source: Based on data from the patient survey undertaken for this paper, using the responses to the ‘how much do you agree with the following statements?’

**Recommendation 5:** The Health Research Authority must ensure that primary care is appropriately represented in the development of their future guidance on ‘identifying and contacting people about research’, which will seek to reduce current variation in the interpretation of the law.

### Direct patient engagement

One way of increasing patient engagement in research is by giving them a more active role. According to Hilary Fanning, “patients should be empowered to identify themselves for trials via websites and apps rather than relying only on sites/GPs identifying them.” Socialising trial opportunities more broadly would increase recruitment”. Survey results show that 88 per cent of patients already receive text messages from their GP and 93 per cent of them would be happy to receive information about participation in clinical research from their GP surgery by text message.

The team at the Clinical Practice Research Datalink have reported increased engagement from patients when they provided further research information. Dr. Tim Williams mentioned the example of an asthma trial where they provided links with more easily digestible information for eligible patients to find out more about the trial itself. They also provided the details of a person who could be contacted to answer questions about the trial. This had a positive impact on enrolment.

**Recommendation 6:** The Royal College of General Practitioners, National Institute for Health and Care Research and the NHS England funded Primary Care Networks should develop guidance that encourages GP practices to use texting services to engage directly with patients about taking part in research. Further information about suitable trials that patients are eligible for should be provided directly to them in order to increase engagement and participation.

#### **4. Allaying concerns about data protection**

Ensuring that data collected within the health and care system is used appropriately when recruiting patients into trials is crucial. According to Hilary Fanning, “building and safeguarding trust between patients, primary care professionals and researchers (from private, public and third sector) is key.”

Dr. Simon Royal explained that the data controllership of the GP and the legal ramifications in case of a breach can make them risk-averse when sharing data for research purposes. He suggested that if there existed an indemnity insurance for GPs that would cover them for the risk associated with being a data controller, GPs would be more likely to allow access to primary care data. However, Emma Lowe and Dr. Janet Messer explained that although some of the liabilities of data protection issues are already transferred through the regulatory review process, this does not cover all the aspects that GPs would be concerned about that are outside the regulatory process.

Roundtable attendees highlighted that GPs often spend a lot of money on legal fees when putting in place a data-sharing agreement. This is because there is a lack of standardisation of data-sharing agreements within primary care, even though some degree of standardisation is possible.

Clear guidance and guidelines for GPs from the Information Commissioners Office are desirable to give GPs greater certainty and reassurance in terms of participation in research activities whilst at the same time helping to ensure that individual’s rights are respected.

## Conclusion

The data held within the health and care system has supported research which has led to pioneering scientific discoveries as well as improvements in the quality of care being delivered to patients. However, there has been growing concern in recent years about the state of clinical research in the NHS, especially for commercial clinical trial activity.<sup>48</sup>

Primary care has a crucial role to play in supporting healthcare research, including clinical trial activity. Whilst progress has been made, with 18 per cent of commercial trial recruitment in England happening in primary care, there is very strong potential to increase this research activity. Doing so will mean overcoming some of the challenges facing primary care such as: difficulties with engaging GPs in research due to overwhelming workload pressures and lack of awareness of studies they could get involved with; as well as challenges in identifying, recruiting, and engaging with patients; and a general wariness of giving access to primary care data for research.

This paper provides six clear and actionable recommendations to address these barriers and encourage increased research activity within primary care.

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<sup>48</sup> Lord James O'Shaughnessy, *Commercial Clinical Trials in the UK: The Lord O'Shaughnessy Review*; Association of British Pharmaceutical Industry, 'Number of Industry Clinical Trials Initiated per Year, by Country (2012-2021)'; Association of British Pharmaceutical Industry, 'Average Number of Participants Treated per Industry Clinical Trial, by Country, by Phase (2018-2020)'.

## Addendum - Roundtable summary

On 16th January 2024, Newmarket Strategy held a roundtable on the topic of the white paper “Harnessing Primary Care Data for Clinical Trial Recruitment”, sponsored by EMIS. James O’Shaughnessy, Senior Partner at Newmarket Strategy gave words of welcome highlighting the key recommendations in his review of Commercial Clinical Trials, the Government’s response to them as well as the key recommendations of this white paper. Dr. Alexander Churchill, Deputy Director, Commercial Clinical Trials at the Department of Health and Social Care gave his opening remarks. This was followed by brief remarks from Dr. Lucy MacKillop, Chief Medical Officer – Data & Research at EMIS and Professor Dame Helen Stokes-Lampard, Professor of GP Education, Birmingham Medical School, University of Birmingham.

There was strong consensus in the roundtable about the untapped potential of primary care data and the wider potential of primary care to contribute to the clinical trial and research agenda. Attendees agreed that there is a moral imperative to use primary care data to enhance clinical research and trial recruitment.

Roundtable attendees recognised that GPs play a crucial role in communicating to patients the importance of participating in research as well as the importance of making data accessible to researchers from the private, public and third sectors to derive insights to improve patient care. Meaningful patient engagement about how data is being used in healthcare is not easy and attendees reflected that it should not be taken as a simple PR campaign or comms exercise. It is about a bottom-up rather than a top-down approach.

Primary care practitioners should see every interaction they have with patients as an opportunity to discuss research and how they could participate in research. Attendees agreed that the sector needs a culture shift and would benefit from having the instinct to “think research” at every interaction.

GPs want to do more research but need to be supported to do so by appropriately compensating primary care practitioner for their efforts as well as providing more training opportunities for staff. Attendees also spoke about a need to homogenise costing across primary and secondary care.

It was noted that the UK is already highly performing in clinical research and in the use of primary care data to inform clinical research compared to countries in Europe. However, it is still capable of much more whether acting alone or – ideally – in research partnerships with community, mental health, secondary, tertiary, and other sectors. Creating these cross-sectoral collaborations is a major focus for the newly commissioned NIHR Research Delivery Networks. The NHS Research Secure Data Environment Network in England also needs to have supporting primary care research as an explicit objective.

Several practical barriers were identified that could be resolved quite easily. The GP contract could be amended so that it more explicitly promotes R&D. Simple prompts, like using patient text messaging or flagging trials at check-ins, are highly effective and low-impact ways that can increase recruitment.



Attendees felt upcoming NIHR research workforce plan needs to include plans to recruit more specialist roles in primary care, for example in data management and analysis, that would make it easier for GPs to carry out R&D. The costs and time required to create bespoke data-sharing agreements for each site for each trial should be eliminated by creating a common approach, and the revamped National Costing and Value Review needs to be made primary care appropriate.

Inevitably some of these changes, as well as other improvements outlined both in this Report and in the O'Shaughnessy Review, will require investment. Attendees suggested that the investment facility in the new voluntary medicines pricing agreement with industry (VPAG) could – in part – be used to improve the capability and capacity of the primary care sector to carry out more research. If this could be focused on supporting commercial trials as a priority, then this would generate much-needed new income streams for the primary care sector as well as contribute to the wider UK life science ecosystem.

Finally, all attendees expressed a strong desire for the primary care sector to be fully included in policymaking around health R&D. Historically this has not always been the case, yet the potential of the sector to contribute to the recovery and rejuvenation of clinical trials demands it should have a seat at the table.

### Roundtable attendee list

- > **Isabel Baker**, Solution Specialist, EMIS
- > **Dr. Alexander Churchill**, Deputy Director, Head of Commercial Clinical Trials, Department of Health and Social Care
- > **Rebecca Cosgriff**, Deputy Director, Data for R&D, NHS Transformation Directorate, NHS England
- > **Rebecca Ghosh**, Clinical Practice Research Datalink Senior Researcher, Medicines and Healthcare products Regulatory Agency
- > **Nicola Hamilton**, Head of Understanding Patient Data, NHS Confederation
- > **Eleonora Harwich**, Director, Newmarket Strategy
- > **Prof. Margaret Ikpoh**, GP Partner, Holderness Health & Vice Chair, Royal College of General Practitioners
- > **Dr. Lucy MacKillop**, Chief Medical Officer – Data & Research, EMIS
- > **Prof Christian Mallen**, National Director of the NIHR School of Primary Care Research, National Institute for Health and Care Research
- > **Prof. Andrew Morris**, Director, Health Data Research UK
- > **Dr. Masood Nazir**, Medical Director Integrated Care and Chief Clinical Information Officer, NHS Birmingham and Solihull ICS
- > **Martin O'Kane**, Regional Head RA EU Policy & Liaison, Novartis
- > **James O'Shaughnessy**, Senior Partner, Newmarket Strategy
- > **Nicola Perrin**, Chief Executive, Association of Medical Research Charities
- > **Arnaud Plantenga**, Consultant, Newmarket Strategy
- > **Prof. Dame Helen Stokes-Lampard**, Professor of GP Education, University Hospitals Birmingham NHS Foundation Trust

- > **Janet Valentine**, Executive Director of Innovation & Research, Association of the British Pharmaceutical Industry
- > **Dr. Colin Wilson**, Deputy Director, Research Infrastructure, Office for Life Sciences
- > **Dr. Ian Wood**, Clinical Director, EMIS

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**Newmarket Strategy Ltd**

Niddry Lodge  
51 Holland Street  
London, W8 7JB

+44 (0) 207 368 1611

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