NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

ANNUAL REPORT 2021

Enabling a trusted national ethics opinion

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Contents

Foreword

Dr Jennifer Ralph James
Head, National Office for Research Ethics Committees

I am delighted to present the second annual report of the National Office for Research Ethics Committees. Reflecting on our first full calendar year of operation, 2021 proved to be a period of important milestones for Ireland's new system of national research ethics review. This report captures a year of launch, growth and focus for both the committee members and the National Office team as we worked to transform an essential infrastructure for health research in Ireland.

In May 2021, a total of 54 volunteer National Research Ethics Committees (NRECs) members were appointed by the Minister for Health. Their selection followed a public campaign for expressions of interest, the first of its kind in Ireland, which was managed by the National Office. We were inspired by the response from 145 individuals for this national endeavour to bolster Irish health research. Testament to the reach of the campaign was the diversity of expertise, backgrounds and lived experiences represented by those putting themselves forward; this included medical expertise, allied health professions, sciences, sociology, law, statistics, ethics, carers, and patient advocacy. With a strong NREC membership now in place, the National Office will continue to promote the diversity and inclusiveness in representation necessary for these committees acting in the public interest. In addition to their expertise, experience and perspectives, the NREC members bring a high level of enthusiasm and dedication to their roles, which protects research participants, strengthens the research system, and ensures a productive partnership with the National Office – and for this we extend heartfelt appreciation to the NREC members.

Preparation for European Union (EU) Regulations for clinical trials and medical devices was a resolute focus for the National Office in 2021. Bringing in harmonisation and improved efficiency and transparency for these research areas across Europe, the regulations require a new degree of national coordination in regulatory and ethics review in Ireland.

> "Our collaborative efforts throughout 2021 have propelled us significantly towards achieving our mission: to embed a robust, transparent and cohesive research ethics review system that strengthens the national research infrastructure in Ireland."
>
> **Dr Jennifer Ralph James**
> Head, National Office for Research Ethics Committees

To this end, we worked in close collaboration with the Health Products Regulatory Authority (HPRA), the national competent authority, throughout 2021 to navigate the opportunities and complexities of a new regulated environment for clinical trials and medical devices. The launch of the NRECs coincided with the application of the Medical Device Regulation (MDR) (Regulation EU 2017/745), meaning that the National Research Ethics Committee for Clinical Investigations of Medical Devices (NREC-MD) was ready to ensure Ireland's compliance with this important legislation. With the EU Clinical Trials Regulation (CTR) pending until January 2022, the National Research Ethics Committee for Clinical Trials of Investigational Medicinal Products (NREC-CT), Committees A and B, worked alongside 'recognised Research Ethics Committees' (RECs) across Ireland to review clinical trials over a period of transition from local to national research ethics review. We are grateful to our colleagues in the HPRA and the local REC community for their collaboration throughout 2021 to prepare the Irish research environment for these important changes, which will ultimately support health outcomes from medical device and clinical trial research, both areas of strategic importance for Ireland.

2021 was certainly 'a year of firsts' for the NREC system, for which continued guidance from the Department of Health was essential and gratefully received. With uncharted territory came ambitious goals and high work momentum for the National Office team, who deserve special mention for their commitment to the mission of the National Office. We are indebted to the standing subcommittee of the NREC-COVID-19, which, through its ethics oversight, ensures that COVID-19 research can continue to address the health research questions posed by the pandemic. We are thankful for the unwavering operational support that our host organisation, the Health Research Board (HRB), continues to provide. While we are still in the early days of our journey, I know that these collaborative efforts throughout 2021 have propelled us significantly towards achieving our mission: to embed a robust, transparent and cohesive research ethics review system that strengthens the national research infrastructure in Ireland.

2021 snapshot

NRECs' work in 2021 at a glance

27 meetings

68 applications

44 decisions*

43 favourable decisions

1 unfavourable decision

36 days average time to decision

150+ studies overseen**

13 therapeutic areas covered

- eye
- cancer and neoplasms
- blood
- respiratory
- infection
- inflammatory and immune system
- oral and gastrointestinal
- skin
- neurological
- congenital disorders
- metabolic and endocrine
- cardiovascular
- renal and urogenital

Committees at a glance

3 committees

55 members***

52% male

48% female

Representing diverse backgrounds, including:

- ethics
- lay
- law
- medical
- sciences and other health care professionals
- industry
- public health
- social sciences
- statistics

From all over Ireland

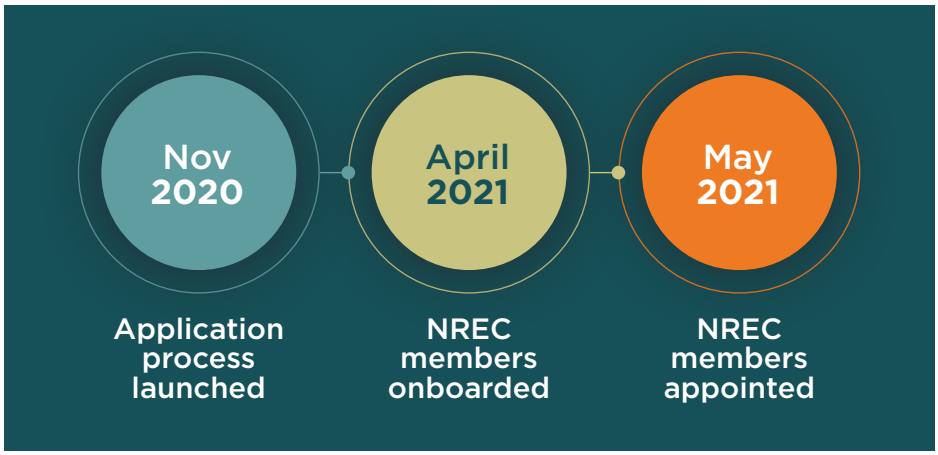
* Difference between applications submitted and decisions reached reflects applications that were invalid or withdrawn before a decision was made

** Includes new studies and studies that have transitioned to the national research ethics system

*** This number includes two committee members who stepped down before the end of 2021 and one further member who was appointed

National Office highlights in 2021

Nationwide campaign to appoint members to three new NRECs



145
expressions of interest received

3
new NRECs

- NREC for Clinical Trials of Investigational Medicinal Products A
- NREC for Clinical Trials of Investigational Medicinal Products B
- NREC for Clinical Investigations of Medical Devices

55
members appointed

Informing – engaging – collaborating

500+
participants in webinar marking NRECs' launch

12+
hours of dedicated training organised for NREC members*

10+
national and international forums where the National Office is represented

* 12 hours of formal training were provided to members, plus additional sessions during committee meetings

The National Office

Our story, our vision and mission, our team

Our story

The National Office for Research Ethics Committees is an important recent addition to the research environment in Ireland. Hosted by the Health Research Board (HRB), the National Office has an independent role in the regulation of health research. Our mission is to embed a robust, transparent and cohesive research ethics review system that strengthens the national research infrastructure.

We are tasked with establishing National Research Ethics Committees (NRECs) in prescribed areas of health research at the request of the Minister for Health. An essential aspect of the NREC system is the mandate to return ethics decisions that are respected nationally ('single national ethics opinion'). Working alongside local research ethics committees and supported by the National Office team, NRECs work in a mixed-model system to support research ethics across the spectrum of health research in Ireland.

The National Office was established in early 2020 as a key component of the reform of the research ethics committee framework in Ireland led by the Department of Health. In partnership with the other regulators of health research, including the Department of Health and the Health Products Regulatory Authority (HPRA), we are implementing a roadmap of transition to a national system of research ethics review for regulated remits, including clinical trials of medicinal products and clinical investigations of medical devices. We are also working closely with local research ethics committees to ensure that this transition is as seamless as possible, in order to maintain research momentum in these important areas.

As an independent office with a statutory function, our role at the National Office includes the following:

- Establishing NRECs in specific areas of health research
- Managing Expressions of Interest for NREC membership
- Providing operational support to NRECs
- Providing guidance and support to applicants
- Issuing guidelines for NREC work
- Delivering education and outreach

Our vision and mission

Our vision and mission are the pillars that will guide our decisions and actions. They focus on how we strengthen and streamline research ethics review in Ireland, and will grow to become a cohesive mixed-model system.

VISION

Ireland's system of research ethics review cultivates the benefits of health research for patients and the public.

Our aspiring vision requires building a robust system for national research ethics review that adheres to the highest ethical principles and standards of efficiency, and in doing so, fosters a health research environment that works with Irish patients and the wider public to deliver tangible health and economic benefits for all.

MISSION

The National Office will embed a robust, transparent and cohesive research ethics review system that strengthens the national research infrastructure.

Our ambitious mission is to bolster the research infrastructure in Ireland and deliver operational excellence by embedding a bespoke and robust national system for research ethics review, based on a commitment to transparency and cohesion. With a steadfast commitment to our vision and mission, we will work to ensure that the dignity, safety and well-being of research participants is front and centre of an NREC system that positions Ireland as the first-choice location for developing new medicines and technologies – all with the goal of improving access to emerging new treatments, cures, and preventions for Irish patients and the wider public.

Our people

The team at the National Office

An efficient and robust NREC system relies on dedicated and tailored operational support. The National Office is a diverse and inclusive workplace, staffed by a dynamic, high-performing team of programme managers, project officers, and an administrative assistant, under the leadership of the Head.

Driven by our values – integrity, transparency, partnership, knowledge, and independence – the National Office team is committed to establishing an agile and trusted office in national public service.

The National Office team represents a variety of professional and life experiences, united by the common goal of supporting a national system of research ethics review and of delivering excellence in public service.

The professional knowledge of our scientific staff means that applicants engage with programme managers and project officers who are familiar with the nuances of the health research environment and can provide guidance, insight, and constructive feedback at appropriate points in the review process to applicants submitting ethics applications. This peer-to-peer engagement can strengthen the implementation of best practice in research ethics in Ireland. Our scientific staff are also well placed to support the NREC membership with expert perspectives on REC operations, informed by international standards and prevailing law. Collectively, our team supports applications throughout the ethics review life cycle, and provides excellence in operational support to the NRECs. The National Office benefits from shared core services, such as communications and information technology (IT), through the HRB, our host organisation.

National Office team members in 2021 included:

Dr Jane Bryant
Project Officer

Dr Jennifer Ralph James
Head, National Office

Kathy Kelly
Administrative Assistant

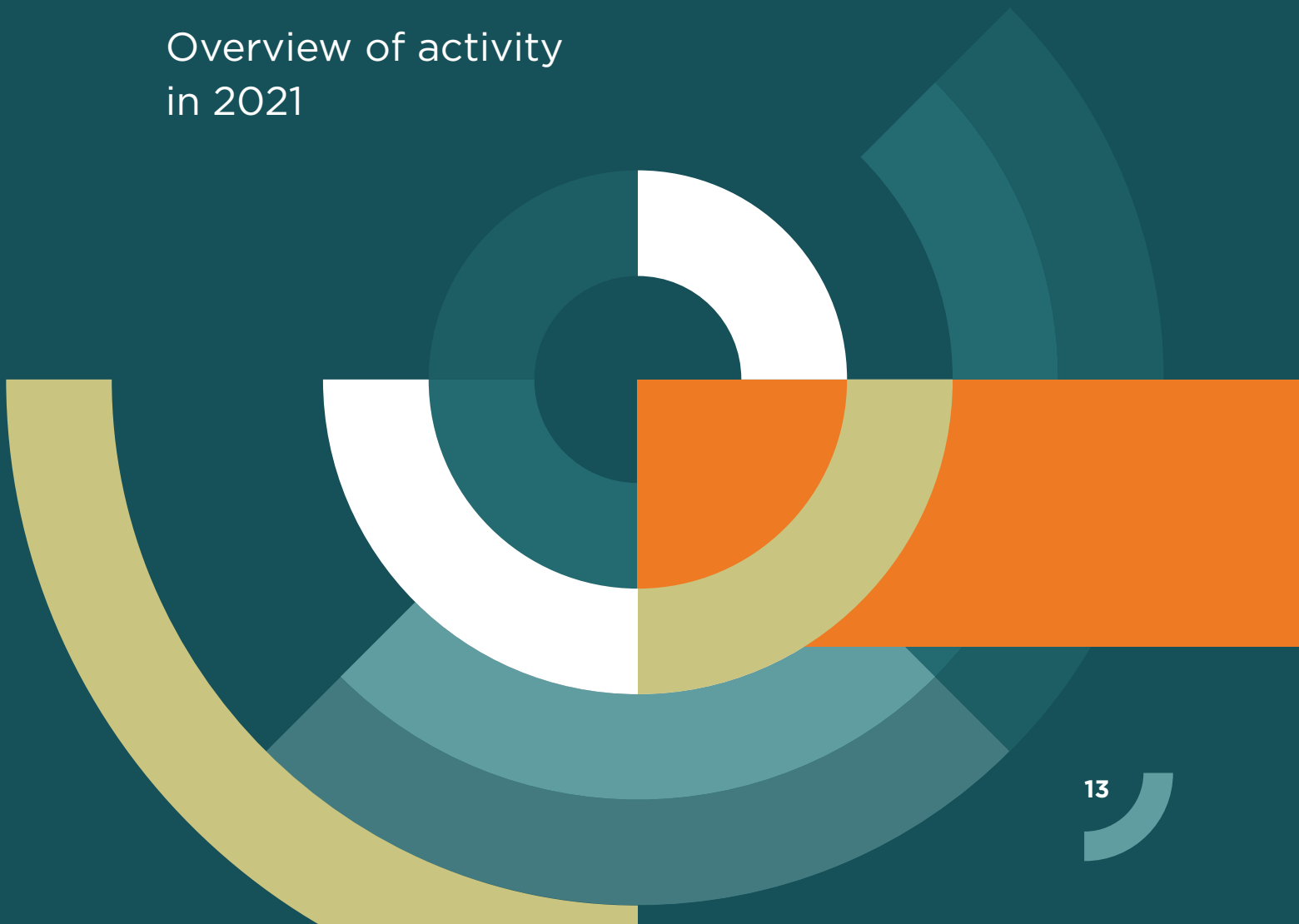
Dr Laura Mackey
Project Officer

Dr Lucia Prihodova
Programme Manager

Aileen Sheehy
Programme Manager

National Research Ethics Committees for Clinical Trials of Investigational Medicinal Products

Overview of activity
in 2021



National Research Ethics Committees for Clinical Trials of Investigational Medicinal Products (NREC-CTs)

In May 2021, two dedicated NRECs were established to meet Ireland's requirements under the EU Clinical Trial Regulation (CTR) (EU) 536/2014 and review ethics applications within the regulated remit of Clinical Trials of Investigational Medicinal Products (CTIMP). The National Research Ethics Committee for Clinical Trials of Investigational Medicinal Products A (NREC-CT A) is chaired by Professor Alistair Nichol, and the National Research Ethics Committee for Clinical Trials of Investigational Medicinal Products B (NREC-CT B) is chaired by Dr Cliona McGovern. Committee members were appointed from all over Ireland, representing a wide variety of professional backgrounds and lived experiences, in order to bring a diverse range of expertise to the ethical review decision-making process.

The NREC-CTs are regulated statutory committees, established by the Department of Health under S.I. No. 190/2004 – European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations, 2004, with the view of taking on the review of all CTIMPs after the transition to the EU CTR implemented in early 2022.[1]

From May 2021, the NREC-CTs ran concurrently with RECs recognised under S.I. 190/2004, to review CTIMP ethics applications.

All new clinical trial applications were reviewed by the NREC-CTs, and ongoing trials previously approved by RECs recognised under S.I. 190/2004 could transition to the NREC-CTs through the submission of a substantial amendment.

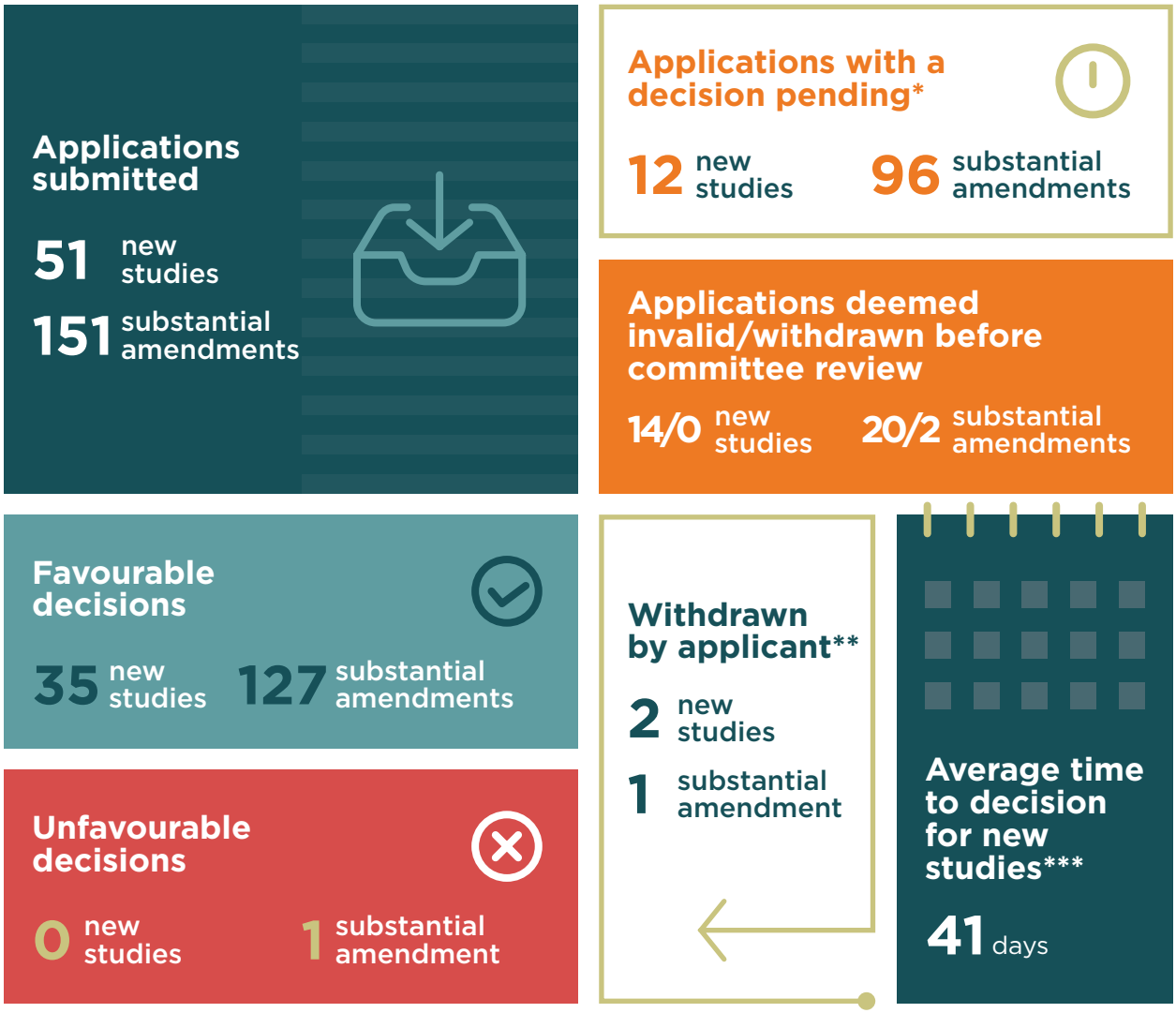
In 2021, the 2 committees met a combined 13 times for main meetings; in addition, a further 6 subcommittee meetings were held. During these meetings, 37 applications for new studies were reviewed, with an average time of 41 days between the date of validation and final decision. A further 128 substantial amendment applications received final decisions over this time period. The majority of applications submitted received a request for further information from the committees before final decisions were made, and the majority of those with a favourable decision had conditions attached.

2021 also saw the launch of the CTR-National Collaboration Project, a joint initiative between the National Office, the NREC-CTs and the HPRA.

1 Since publication of this Annual Report, statutory instrument S.I. 41 of 2022 recognises the NREC-CTs under Irish legislation.

This project tested the national preparedness in advance of the implementation of the CTR and laid the foundations for how both the National Office and the HPRA work together to ensure an efficient and coordinated national response to the CTR. The project ran between June and December and four clinical trials were reviewed under the joint initiative.

At a glance: NREC-CTs' work in 2021



* Applications submitted up to December 2021 and pending a NREC decision were subsequently reviewed in 2022

** Withdrawn after request for further information (RFI) decision issued

*** Data not collated for substantial amendment applications

Message from the Chairperson, NREC-CT A

Professor Alistair Nichol
Chairperson, NREC-CT A
and Consultant Anaesthetist
and Intensivist, St. Vincent's
University Hospital

The establishment of the NREC-CTs in May 2021 has been a long-awaited and necessary step in the Irish clinical research environment to address the vital need for a national, harmonised, independent ethical review. Our central role is to protect patients taking part in regulated clinical trials and to ensure that participant well-being is placed at front and centre of clinical research in Ireland.

The NREC-CT A, in partnership with our sister committee, NREC-CT B, is achieving this by aligning on key ethical issues and providing standardised feedback to the research community working on clinical trials of investigational medicinal products.

Over the coming years, we expect that the feedback and aligned approaches currently being developed will feed into national best practices and policies to ensure the highest level of protection and transparency for research participants.

Our committees bring together people from different disciplines across Ireland to consider and deliberate on ethical issues related to clinical trials. The cross-disciplinary review process, which includes patient and public reviewers, bolsters the rigour of the NREC-CT ethics review process and enhances the protection of research participants.

As we transition to a new legislative environment for clinical trials in 2022, the NREC-CT A will continue to work in an agile and flexible way for the benefit of the whole of Irish society. We will ensure that all legislative requirements are met while continuing to place the safety and well-being of Irish research participants at the centre of the review process.

Although only in place since May 2021, we anticipate that the continued efforts of the NREC-CTs will not only make Ireland a more attractive destination for international clinical trials but will promote public confidence in clinical research and provide the Irish population with essential access to vital experimental treatments.

NREC-CT A COMMITTEE MEMBERS

The following committee members served on the NREC-CT A in 2021:

Prof. Alistair Nichol
Chairperson
St. Vincent's University Hospital

Prof. Mary Donnelly
Deputy Chairperson
University College Cork

Dr Heike Felzmann
Deputy Chairperson
National University of Ireland, Galway

Dr Darren Dahly
Member
HRB Clinical Research Facility University College Cork

Prof. Patrick Dillon
Member
University Hospital Limerick

Dr Jimmy Devins
Member
Retired GP

Prof. John Wells
Member
Waterford Institute of Technology

Prof. Catherine Hayes
Member
Trinity College Dublin

Dr Tina Hickey
Member
University College Dublin/ patient advocate

Dr Dervla Kelly
Member
University of Limerick

"Ethical governance is a key component in reassuring the public that medical research will be scrutinised in relation to the public good. My involvement in NREC has provided me with the opportunity to work with national experts who are committed to the public good by advising clinical researchers as to the highest ethical standards in the practice of medical research in Ireland."

Professor John Wells
Member of NREC-CT A; Dean, School of Health Sciences, Waterford Institute of Technology

Dr Geraldine Foley
Member
Trinity College Dublin

Prof. David Brayden
Member
University College Dublin

Dr John O'Loughlin
Member
Retired medical scientist

Ms Muireann O'Briain
Member
Retired barrister

Mr Gerard Daly
Member
Retired civil servant

Mrs Ann Twomey
Member
The Alzheimer Society of Ireland

Prof. Eugene Dempsey
Member
University College Cork/ Cork University Maternity Hospital

Prof. Mark Sherlock
Member
Beaumont Hospital

Prof. Orla Sheils
Member
Trinity College Dublin

Message from the Chairperson, NREC-CT B

Dr Cliona McGovern
Chairperson, NREC-CT B
and Head of Subject of Forensic and Legal Medicine, University College Dublin

The role of the newly appointed NREC-CTs has been to provide a single national ethics opinion on clinical trial applications in Ireland. Over the short period since our establishment, the committees have shown that they are providing leadership and consensus nationally on complex ethical issues.

With the EU CTR due to be implemented in early 2022, much of the additional work placed on the NREC-CTs in 2021 focused on the preparation for the significant change to the legislative landscape, and in turn, necessary changes to ethics assessment processes ahead.

The NREC Chairpersons and Deputy Chairpersons worked closely with the National Office, the Department of Health, and the HPRA on key aspects of secondary legislation that would transpose the CTR into national legislation. This has ensured that the rights and safety of research participants continue to be protected under the new legislation and that the committees have the flexibility to determine their own processes while meeting the strict requirements of the CTR.

The NREC-CTs worked with the HPRA on testing national preparedness through the joint initiative, the CTR National Collaboration Project, in advance of the CTR coming into effect. The learnings from this collaboration have fed into adjustments in how the newly established committees can adapt their processes to reflect the fundamental changes to the review process under this new and complex legislation.

The strong working collaborations and relationships built through these initiatives have placed Ireland in a strong and agile position to manage the transitionary period, and have laid strong foundations for the NREC-CTs to confidently continue to protect research participants while ensuring that important clinical trials continue to take place in Ireland.

Over the coming year, we look forward to working with the Department of Health on other key projects such as the development and implementation of the National Research Ethics Committees Bill.

NREC-CT B COMMITTEE MEMBERS

The following committee members served on the NREC-CT B in 2021:

Dr Cliona McGovern
Chairperson
University College Dublin

Dr Jean Saunders
Deputy Chairperson
Claddagh Statistical Consultancy Services

Prof. John Faul
Deputy Chairperson
Connolly Hospital Blanchardstown

Dr Enda Dooley
Member
Mental Health Commission

Prof. David Smith
Member
Royal College of Surgeons in Ireland

Dr Mary McDonnell Naughton
Member
Athlone Institute of Technology

Dr Eimear McGlinchey
Member
Trinity College Dublin

Ms Paula Prendeville
Member
National Council for Special Education

Dr John Hayden
Member
Royal College of Surgeons in Ireland

Mr Gavin Lawler
Member
Beacon Hospital

"As someone who manages the development and implementation of the Health Service Executive (HSE) National Consent Policy, I place a high value on informed consent and data protection. I was motivated to join NREC in order to bring this experience to the committee and work to ensure that research participants are afforded the best opportunity to provide informed consent in clinical trials."

Caoimhe Gleeson
Member of NREC-CT B; National Programme Manager, HSE National Office for Human Rights and Equality Policy

Dr Mark Robinson
Member
National University of Ireland, Maynooth

Prof. Abhay Pandit
Member
CÚRAM, SFI Research Centre for Medical Devices

Dr Lorna Fanning
Member
Career break (pharmaceutical industry)

Ms Serena Bennett
Member
Barrister

Ms Mandy Daly
Member
Irish Neonatal Health Alliance

Mr Philip Berman
Member
Retired, Hospital Services Policy and Management

Ms Caoimhe Gleeson
Member
HSE National Office for Human Rights and Equality Policy

Prof. Colm O'Donnell
Member
National Maternity Hospital

National Research Ethics Committee for Clinical Investigations of Medical Devices

Overview of activity in 2021

National Research Ethics Committee for Clinical Investigations of Medical Devices (NREC-MD)

The National Research Ethics Committee for Clinical Investigations of Medical Devices (NREC-MD) was established in May 2021 to meet Ireland's requirements under the EU Medical Device Regulation (MDR) (EU) 2017/745. The first committee meeting was held on 27 May 2021.

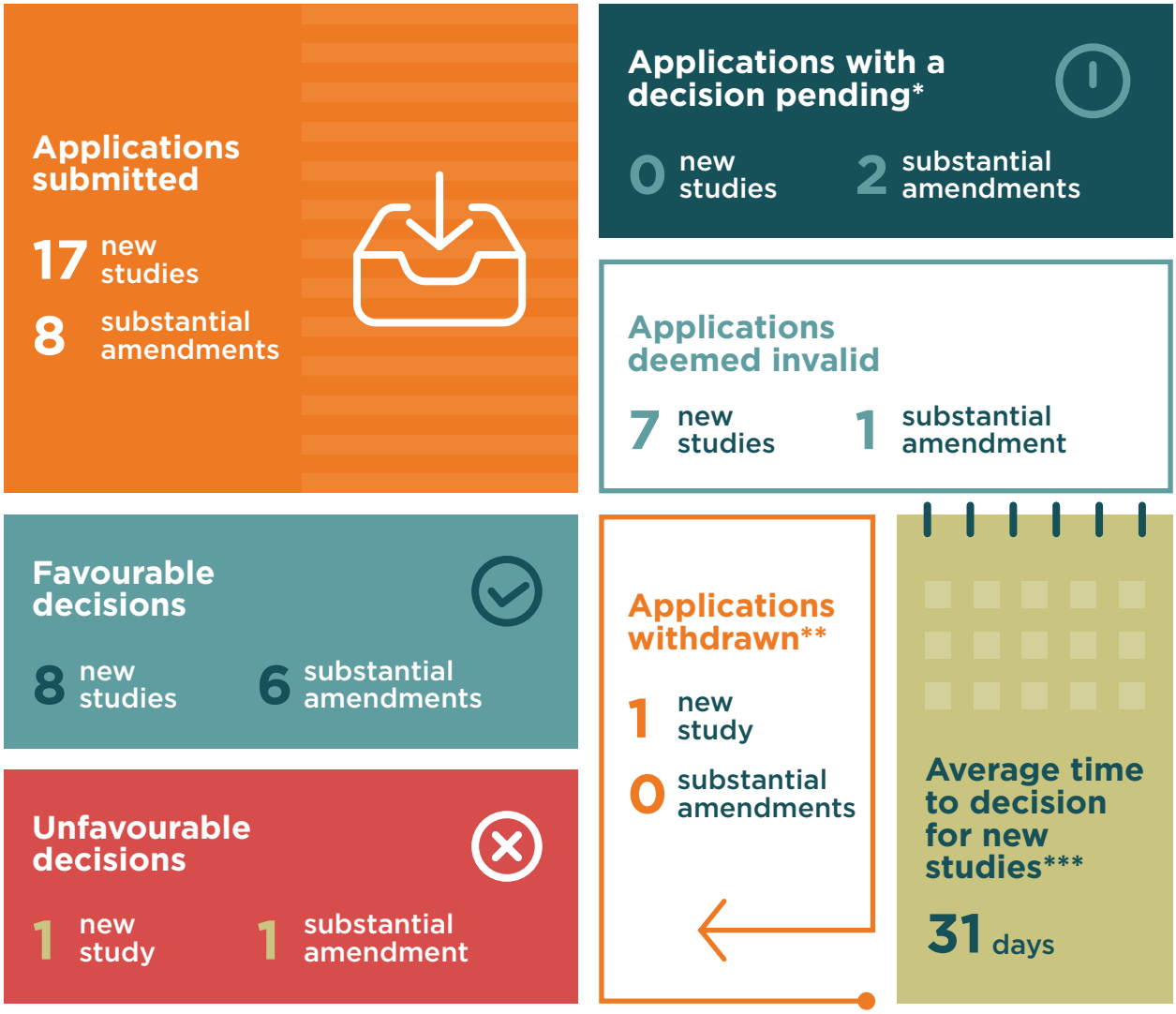
The NREC-MD is established by the Department of Health under S.I. No. 260/2021 European Union (National Research Ethics Committee for Clinical Investigations of Medical Devices) Regulations 2021 and provides a single national opinion on ethics applications related to clinical investigations of medical devices as defined in the MDR.

In 2021, the committee reviewed 10 applications for new studies and 7 applications for a substantial amendment of already approved clinical investigations, with an average time of 31 days from submission to decision for applications for new studies. The majority of applications submitted received a request for further information (RFI) from the committees before final decisions were made, and of those deemed favourable, the majority had conditions attached.

The committee is chaired by Professor Barry O'Sullivan, Professor of Artificial Intelligence at the School of Computer Science & IT, University College Cork. Committee members have extensive experience across various backgrounds, ranging from lived experience as patients to backgrounds in medicine, healthcare, law, and science. Thanks to this diverse spectrum of expertise, each application benefits from a comprehensive, robust, and efficient review.

Since the committee's establishment in May, members came together for a total of eight meetings over the course of 2021, dedicating significant time and effort to the review of applications, which is helping to pave the way for medical innovations for Irish patients.

At a glance: NREC-MD's work in 2021



* Applications submitted up to December 2021 and pending a NREC decision were subsequently reviewed in 2022

** Withdrawn after RFI decision issued

*** Data not collated for substantial amendment applications

Message from the Chairperson, NREC-MD

Professor Barry O'Sullivan
Chairperson, NREC-MD and Professor of Artificial Intelligence, School of Computer Science & IT, University College Cork

Ireland is a major research hub for the medical device industry. This is an industry that is subject to significant regulatory oversight, including the European Union's MDR. This regulation represents a significant strengthening of the existing regulatory system for medical devices in Ireland and across Europe.

The first meeting of the NREC-MD was held in May 2021, one day after the MDR came into force, thereby demonstrating the agility of the National Research Ethics Committee system in meeting the EU's regulatory requirements.

As the only research ethics committee recognised in Ireland under the MDR, the NREC-MD is responsible for considering the ethical aspects that might arise in research proposals for all clinical investigations related to medical devices, new and ongoing, and in each case for issuing a single authoritative ethics opinion that is respected and valued nationally and internationally.

As such, the NREC-MD plays a key role in protecting the safety, dignity, and well-being of health research participants in Ireland. A national approach to research ethics is helping us create an integrated and supportive environment for the community to deal with the complex ethical and regulatory issues that arise in the development of medical devices.

In the face of the new regulation, it is important that we work together and create a strong research ethics culture in the relevant areas. Over the last year, the NREC-MD has worked closely with the National Office for Research Ethics Committees, the Medical Device Division of the Health Products Regulatory Authority, and the Department of Health, to ensure that a smooth, agile and robust ethics review process is in place.

It has been an honour for me to chair the NREC-MD. It has been a pleasure to work with the members of the Committee, whose engagement and thorough assessment and comprehensive deliberation of each of the proposals we received have been enhanced by the diverse expertise, varied experience, and strong commitment to research ethics of each of the Committee members.

I look forward to another productive and impactful year ahead, as in 2022 the NREC-MD will also begin delivering the ethics reviews required to operationalise the *In Vitro* Diagnostic Medical Devices Regulation.

I would like to take this opportunity to personally thank each and every member of the NREC-MD for their commitment to the highest standards. I would also like to sincerely thank the staff of the National Office for Research Ethics Committees for providing such amazing support and guidance, without which it would be impossible to complete our work so effectively and efficiently.

NREC-MD COMMITTEE MEMBERS

The following committee members served on the NREC-MD in 2021:

Prof. Barry O'Sullivan
Chairperson
University College Cork

Prof. Mary Sharp
Deputy Chairperson
Trinity College Dublin

Prof. Cathal O'Donnell
Deputy Chairperson
National Ambulance Service

Prof. Mahandra Varma
Member
Retired cardiologist

Dr Paul O'Connor
Member
National University of Ireland, Galway

Prof. Declan Patton
Member
Royal College of Surgeons in Ireland

Prof. Anne Parle-McDermott
Member
Dublin City University

Dr Catherine O'Neill
Member
Semi-retired senior lecturer/researcher in nursing

> "The hope research can offer a patient is hard to quantify and is often overlooked."
>
> **Billy McCann**
> Member of NREC-MD; retired; patient advocate

Dr Caitriona Cahir
Member
Royal College of Surgeons in Ireland

Prof. Thérèse Murphy
Member
Queen's University Belfast

Dr Owen Doody
Member
University of Limerick

Ms Riona Tumelty
Member
Tallaght University Hospital

Mr Peter Woulfe
Member
Galway Clinic

Prof. Susan O'Connell
Member
Children's Health Ireland at Crumlin

Dr Frank Houghton
Member
Limerick Institute of Technology

Mr Billy McCann
Member
Retired; patient advocate

Ms Orla Lane
Member
Economist

Mr Damien Owens
Member
Engineers Ireland

National Research Ethics Committee for COVID-19

Overview of activity of standing subcommittee's work in 2021

NREC COVID-19

In 2020, as part of Ireland's response to the COVID-19 pandemic, and in accordance with a recommendation in the World Health Organization's *A Coordinated Global Research Roadmap: 2019 Novel Coronavirus*, the then Minister for Health established a temporary National Research Ethics Committee (NREC) for COVID-19, to deliver an expedited process for review of COVID-19-related health research.

The research approved by the NREC COVID-19 not only had national significance, it also highlighted Ireland's role in driving internationally relevant COVID-19-related research. The tenure of the NREC COVID-19 came to an end in August 2020.

A standing subcommittee continued to meet for oversight and related responsibilities with regard to studies approved by the NREC COVID-19, with the support of the National Office team. The NREC COVID-19 standing subcommittee includes the Chairperson, Professor Mary Horgan, and the two Deputy Chairpersons, Professor Hannah McGee and Professor Anthony Staines.

The current primary focus of the standing subcommittee is the review of substantial amendments of studies that received approval from the NREC COVID-19. On occasion, additional members of the NREC COVID-19 are co-opted to support the review of substantial amendments.

Between January and December 2021, the standing subcommittee reviewed 25 substantial amendments. On two occasions, the standing subcommittee co-opted additional members to complement the review process.

National Office strategic priorities:

impact to date and priorities for 2022

As a highly anticipated addition to health research infrastructure and with an ambitious brief, it is essential that the National Office for Research Ethics Committees maintains a sharp focus on its distinct new role in supporting health research. The regulatory and ethics considerations for health research can be complex, so it is essential that the National Office and the NRECs add cohesion and clarity to the research environment.

We are committed to driving the transition to a national system for research ethics review for health research remits of strategic importance for Ireland. The NRECs work alongside local RECs in a mixed-model system to support the spectrum of health research through rigorous independent review in a timely and transparent manner. We have identified five strategic priorities to guide the NREC system, which we were able to significantly advance in 2021.

Strategic Priorities

01 **To deliver a robust and transparent system** for NRECs that provides competent and timely ethics review.

02 **To partner with health research stakeholders** with the mutual objective of ensuring that Ireland's ethics review framework is poised to adopt international best-practice and change.

03 **To engage with the research ethics committees community,** researchers and the wider public to facilitate education on ethical decision-making.

04 **To be a thought-leader in the research ethics arena** by seeding discussion, advancing debate, and providing trusted information.

05 **To be an agile and trusted office** in national public service.

The summary below sets out several key actions taken in 2021 under each strategic priority, and provides a snapshot of how we plan to continue to address each focus area in 2022.

1. To deliver a robust and transparent system for NRECs that provides competent and timely ethics review

Update in 2021:

- Made a recommendation to the Minister for Health for the appointment to Ireland's first NRECs in clinical trials and medical devices.
- Launched a public Expression of Interest campaign, with a robust assessment process, the first of its kind in Ireland – which led to the appointment of 54 members.
- Virtually onboarded and trained the NREC members, who are located across the island of Ireland.
- Launched and operationalised the NREC-MD to ensure robust decision-making under the EU Medical Device Regulation (Regulation EU 2017/745) from its implementation in May 2021.
- Launched and operationalised the NREC-CT (Committees A and B) to ensure robust decision-making, in line with the imminent EU Clinical Trials Regulation (CTR; Regulation EU 536/2014).

Next steps for 2022:

- The National Office will ensure that the committees' membership includes the expertise and perspectives necessary to enable robust research ethics review for the expanding remits of the NRECs.
- The National Office will ensure that NREC members, as representatives of contemporary Irish society, are as informed as possible about complex ethics issues and are at the forefront of research developments through education and training.
- We will continue to support the essential work of the NREC-CT and NREC-MD.
- In anticipation of implementation of the EU *In Vitro* Diagnostic Medical Devices Regulation (IVDR; Regulation EU 2017/746) in May 2022, the National Office will work in partnership with the Department of Health to establish a national mechanism of ethics review for this distinct research area.
- In partnership with the Department of Health, we will develop a national mechanism for research ethics review of studies involving ionising radiation, as a regulated health research remit.
- The National Office will begin to characterise the business requirements for a bespoke IT system to support the efficient receipt and management of applications for NREC review.

2. To partner with health research stakeholders with the mutual objective of ensuring that Ireland's ethics framework is poised to adopt international best practice and change

Update in 2021:

- Volunteered with our HPRA colleagues to undergo assessment (known as 'Union Controls') by the European Commission of our national preparedness and compliance in advance of the implementation of the EU CTR.
- Implemented the CTR National Collaboration Project, in partnership with the HPRA, to test national preparedness for the CTR, including the necessary coordination of regulatory and ethics review processes.
- Participated in a HPRA-led webinar series to ensure understanding of the role of the NREC-CT in enabling Ireland's transition to harmonised assessment under the CTR.
- Led establishment of the CTR Knowledge Exchange Working Group to facilitate shared learnings between our EU counterparts on national approaches to ethics review and processes under the CTR.
- Participated as a CTIS Master Trainer to ensure informed and timely upskilling in the new EU portal, the Clinical Trial Information System (CTIS).
- Actively engaged with key stakeholders in the Irish health research environment, including the Irish Health Research Forum, the HSE-led Local REC Reform Working Group, Cancer Trials Ireland (CTI), and the Irish Pharmaceutical Healthcare Association (IPHA).
- Represented Ireland's interests at a European level at key research ethics fora, including the European Network of Research Ethics Committees (EUREC) and the European Medicines Agency-led European Clinical Trials Expert Group.

Next steps for 2022:

- The National Office will maintain representation on key European working groups to ensure that timely and accurate knowledge continually informs Ireland's implementation of EU health research regulations and application of best practice.
- We will continue to connect with patient advocacy organisations, including the Irish Platform for Patient Organisations, Science and Industry (IPPOSI) and Health Research Charities Ireland (HRCI), to ensure that the NREC system is centred on the research participant and the patient, ensuring appropriate public, patient and carer involvement (PPI) representation on the NRECs.
- With the broader context for the Irish research environment in mind, we will engage with discussions on other key considerations for ethical health research, including open science and research integrity.

3. To engage with the REC community, researchers, and the wider public to facilitate education on ethical decision-making

Update in 2021:

- Hosted a student placement that provided meaningful work experience.
- Partnered with the National University of Ireland, Maynooth through the Project Live initiative to collaborate with a Master of Science class to develop education and outreach materials.
- Informed by NREC discussions and review outcomes, we developed applicant guidance materials to improve research ethics applications.
- Operated an efficient 'help desk' and met with prospective applicants from time to time to assist researchers where appropriate with their applications, informed by the practical guidance and experience of the National Office team.
- Represented the National Office and the NRECs at several conferences and events to foster understanding of the role of the NREC system, including the CTI Cancer Retreat 2021, the HRB Grant Holders Conference, the annual Cystinosis Dublin Workshop, Acquired Brain Injury REC Annual Meeting, and the Irish Research Nurses & Midwives Annual Conference.

Next steps for 2022:

- The National Office will host a student placement to enable insight into the role of research ethics as an important regulatory component of health research.
- We will host a HRB postdoctoral intern to provide first-hand experience of working in a health research regulation agency, alongside the experienced National Office team.
- We will continue to seek opportunities to partner with educational stakeholders to foster public understanding of the role of research ethics review as an enabler of health research and its outcomes.
- Consistent with the scope of our remit in education and outreach, we will continue to share learnings and best practice in research ethics review with local RECs.
- We will continue to provide tailored resources for researchers, research participants, students, and the wider public, to improve understanding of research ethics throughout society.

4. To be a thought leader in the ethics arena by seeding discussion, advancing debate, and providing trusted information

Update in 2021:

- Through a public webinar, introduced the National Office and the NRECs and explained the new national system of research ethics review to more than 500 attendees.
- Provided guidance to researchers on the complex area of data protection considerations for research ethics applications, and on best practices in open research.

Next steps for 2022:

- The National Office team will stay abreast of regulations and guidelines relevant to research ethics and developments in the health research environment, so as to establish ourselves as a trusted resource for information for the research community.
- The National Office will facilitate a keynote talk on research ethics at an educational forum, accessible to all.

5. To be an agile and trusted office in national public service

Update in 2021:

- Operationalised the NREC COVID-19 standing subcommittee as an enduring component of the national coordinated research response to the pandemic. This subcommittee provides ethics oversight of the research approved by the NREC COVID-19 in order to ensure that Irish research continues to rapidly address the health research questions posed by the pandemic.
- Further improved the National Office for Research Ethics Committees website for content and accessibility, in order to ensure that it is maintained as an important tool for trusted information and transparency in NREC work.
- Recruited additional key team members to resource the National Office in the strategic and operational elements of its remit.

Next steps for 2022:

- As an important component of Ireland's response to the COVID-19 pandemic, the National Office will continue to support the NREC COVID-19 subcommittee, including the provision of a national mechanism for ethics review for the National Irish COVID-19 Biobank (NICB).
- We will continue to improve our website to ensure that it is a reliable platform for trusted and timely information on research ethics for everyone.
- We will recruit the additional team members required to ensure that a core high-performing National Office team is in place as the remits of the NRECs expand. Moreover, we will attract and retain the best staff in scientific research management.
- Informed by our experience of NREC COVID-19, we will remain agile and responsive to the dynamics of the research environment as it evolves with the challenges and opportunities to come in 2022.
- As the NREC system responds to the needs of the research environment, we will strengthen our transparent communications to the research community and wider public.

Appendices

Appendix I.

Overview of applications for new studies reviewed by NREC-CT A and NREC-CT B in 2021

NREC Reference ID	Study title	National Principal Investigator	Institution	Sponsor	Meeting date	Final decision
21-NREC-CT-001	Phase Ib/II Trial of Pembrolizumab (MK-3475) Combination Therapies in Metastatic Castration-Resistant Prostate Cancer (mCRPC) (KEYNOTE-365)	Prof. Sean Raymond McDermott	Tallaght University Hospital	Merck Sharp & Dohme	02/06/2021	Favourable
21-NREC-CT-002	A Phase 3, Multi-Center, Double-Blind, Randomized, Placebo-controlled Trial to Evaluate the Efficacy and Safety of Reldesemtiv in Patients with Amyotrophic Lateral Sclerosis (ALS)	Prof. Orla Hardiman	Beaumont Hospital	Cytokinetics, Inc.	02/06/2021	Favourable
21-NREC-CT-003	An Open-label, Sequential, Ascending, Repeated Dose-finding Study of Sarilumab, Administered with Subcutaneous (SC) Injection, in Children and Adolescents, Aged 1 to 17 Years, with Systemic Juvenile Idiopathic Arthritis (sJIA), Followed by an Extension Phase	Dr Orla Killeen	Children's Health Ireland at Crumlin	Sanofi-Aventis Recherche et Développement	02/06/2021	Favourable
21-NREC-CT-004	DEXTERITY-AFP: Perivenous Dexamethasone Therapy: Examining Reduction of Inflammation after Thrombus Removal to Yield Benefit in Acute Femorpopliteal DVT (CIP0217)	Prof. Gerard O'Sullivan	University Hospital Galway	Mercator MedSystems, Inc.	16/06/2021	Favourable
21-NREC-CT-005	DEXTERITY-SCI: Perivenous Dexamethasone Therapy: Examining Reduction of Inflammation after Thrombus Removal to Yield Benefit in Subacute and Chronic Iliofemoral DVT (CIP0218)	Prof. Gerard O'Sullivan	University Hospital Galway	Mercator MedSystems, Inc.	16/06/2021	Favourable

NREC Reference ID	Study title	National Principal Investigator	Institution	Sponsor	Meeting date	Final decision
21-NREC-CT-007	A phase III, randomized, double-masked, placebo controlled, parallel-group, multicenter study of the safety and efficacy of OT-101 (Atropine 0.01%) in treating the progression of myopia in pediatric subjects	Prof. Daniel Ian Flitcroft	Technological University Dublin and Mater Misericordiae University Hospital	Ocumension (Hong Kong) Limited	16/06/2021	Favourable
21-NREC-CT-011	A phase III, multicenter, randomized, double blind, placebo-controlled study evaluating the efficacy and safety of canakinumab versus placebo as adjuvant therapy in adult subjects with stages AJCC/UICC v. 8 II-IIIA and IIIB (T>5cm N2) completely resected (R0) non-small cell lung cancer (NSCLC)	Dr Jarushka Naidoo	Beaumont Hospital	Novartis Pharma AG (TRIO CRO)	07/07/2021	Favourable
21-NREC-CT-012	A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Tafasitamab Plus Lenalidomide in Addition to Rituximab Versus Lenalidomide in Addition to Rituximab in Patients With Relapsed/ Refractory (R/R) Follicular Lymphoma Grade 1 to 3a or R/R Marginal Zone Lymphoma	Dr Amjad Hayat	University Hospital Galway	Incyte Corporation	07/07/2021	Favourable
21-NREC-CT-013	A Phase 3, Randomized, Multicenter, Open-label Study Comparing Iberdomide, Daratumumab and Dexamethasone (IberDd) versus Daratumumab, Bortezomib, and Dexamethasone (DVd) in Subjects with Relapsed or Refractory Multiple Myeloma (RRMM)	Dr Patrick Hayden	St James's Hospital	Celgene Corporation	07/07/2021	Favourable
21-NREC-CT-014	An Open-label, Randomized, Phase 3 Study of MK-6482 in Combination with Lenvatinib (MK-7902) vs Cabozantinib for Second-line or Third-line Treatment in Participants with Advanced Renal Cell Carcinoma Who Have Progressed After Prior Anti-PD-1/L1 Therapy	Prof. Sean Raymond McDermott	Tallaght University Hospital	Merck Sharp & Dohme Corp	07/07/2021	Favourable

NREC Reference ID	Study title	National Principal Investigator	Institution	Sponsor	Meeting date	Final decision
21-NREC-CT-020	A multicenter, randomized, double-blind, placebo-controlled study to investigate the efficacy and safety of FAB122 in patients with Amyotrophic Lateral Sclerosis ADORE (ALS Deceleration with ORal Edaravone) study	Prof. Orla Hardiman	Beaumont Hospital	Ferrer Internacional S.A.	21/07/2021	Favourable
21-NREC-CT-021	A Phase 3, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of Deucravacitinib in Participants with Active Psoriatic Arthritis who are Naïve to Biologic Disease-modifying Anti-rheumatic Drugs	Prof. Douglas Veale	St. Vincent's University Hospital	Bristol Myers Squibb International Corporation	21/07/2021	Favourable
21-NREC-CT-022	A phase III, randomized, double-blind, placebo-controlled, multicenter trial to evaluate the safety and efficacy of AMX0035 versus placebo for 48-week treatment of adult patients with Amyotrophic Lateral Sclerosis (ALS)	Prof. Orla Hardiman	Beaumont Hospital	Amylyx Pharmaceuticals	21/07/2021	Favourable
21-NREC-CT-023	TRIO045/LidERA: A phase III, randomized, open-label, multicenter study evaluating the efficacy and safety of adjuvant giredestrant compared with physician's choice of adjuvant endocrine monotherapy in patients with estrogen receptor-positive, HER2-negative, early breast cancer	Prof. Janice Walshe	St. Vincent's University Hospital	F. Hoffmann-La Roche Ltd	21/07/2021	Favourable
21-NREC-CT-038-NPC	Phase III postneoadjuvant study evaluating Sacituzumab Govitecan, an Antibody Drug Conjugate in primary HER2-negative breast cancer patients with high relapse risk after standard neoadjuvant treatment – SASCIA.	Prof. Patrick Morris	Beaumont Hospital	GBG Forschungs GmbH	21/07/2021	Favourable
21-NREC-CT-046-NCP	A Phase 3, Randomized, Open-Label, Controlled, Multicenter Study of Zandelisib (ME-401) in Combination with Rituximab Versus Standard Immunochemotherapy in Patients with Relapsed Indolent Non-Hodgkin's Lymphoma (iNHL) – The COASTAL Study	Prof. Elisabeth Vandenberghe	St James's Hospital	MEI Pharma, Inc	11/08/2021	Favourable

NREC Reference ID	Study title	National Principal Investigator	Institution	Sponsor	Meeting date	Final decision
21-NREC-CT-047	A comparison of reduced dose total body irradiation (TBI) and cyclophosphamide with fludarabine and melphalan reduced-intensity conditioning in adults with acute lymphoblastic leukaemia (ALL) in complete remission	Dr Larry Bacon	St James's Hospital	University of Birmingham	11/08/2021	Favourable
21-NREC-CT-048	A Randomized Phase 3 Study of MRTX849 versus Docetaxel in Patients with Previously Treated Non-Small Cell Lung Cancer with KRAS G12C Mutation	Dr Jarushka Naidoo	Beaumont Hospital	Mirati Therapeutics, Inc.	11/08/2021	Favourable
21-NREC-CT-049	A Randomized Phase 3 Study of MRTX849 in Combination with Cetuximab Versus Chemotherapy in Patients with Advanced Colorectal Cancer with KRAS G12C Mutation with Disease Progression On or After Standard First-Line Therapy	Prof. Sean Raymond McDermott	St. Vincent's University Hospital	Mirati Therapeutics, Inc.	11/08/2021	Favourable
21-NREC-CT-069	A Phase 1/2 non-randomized, open-label, multi-cohort, multi-center study assessing the clinical benefit of SAR444245 (THOR-707) combined with cemiplimab for the treatment of participants with advanced unresectable or metastatic skin cancers	Prof. John Crown	St. Vincent's University Hospital	Sanofi-Aventis Recherche et Développement	11/08/2021	Favourable
21-NREC-CT-070	A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study Comparing Niraparib Plus Pembrolizumab Versus Placebo Plus Pembrolizumab as Maintenance Therapy in Participants Whose Disease has Remained Stable or Responded to First-Line Platinum-Based Chemotherapy with Pembrolizumab for Stage IIIB or IV Non-Small Cell Lung Cancer	Dr Dearbhaile Collins	Cork University Hospital	GlaxoSmithKline	01/09/2021	Favourable

NREC Reference ID	Study title	National Principal Investigator	Institution	Sponsor	Meeting date	Final decision
21-NREC-CT-071	A Pivotal Phase 3 Randomized, Placebo-controlled Clinical Study to Evaluate the Efficacy and Safety of the sGC Stimulator Vericiguat/MK-1242 in Adults With Chronic Heart Failure With Reduced Ejection Fraction.	Prof. Kenneth McDonald	St Michael's Hospital	Merck Sharp & Dohme	01/09/2021	Favourable
21-NREC-CT-083	A Randomized, Open-Label Study of the Efficacy and Safety of Galinpepimut-S (GPS) Maintenance Monotherapy Compared to Investigator's Choice of Best Available Therapy in Subjects with Acute Myeloid Leukemia Who Have Achieved Complete Morphological Remission After Second-Line Salvage Therapy	Dr Janusz Krawczyk	University Hospital Galway	Sellas Life Sciences Group, Inc.	22/09/2021	Withdrawn
21-NREC-CT-084	A Randomized Multicenter Phase 3 Study of Milademetan Versus Trabectedin in Patients with Dedifferentiated Liposarcoma	Prof. Mark Doherty	St. Vincent's University Hospital	Rain Therapeutics, Inc.	22/09/2021	Favourable
21-NREC-CT-085	A Phase 2 Study to Evaluate the Efficacy and Safety of MK-1026 in Participants with Hematologic Malignancies	Prof. Patrick Thornton	Beaumont Hospital	Merck Sharp & Dohme Corp	22/09/2021	Withdrawn
21-NREC-CT-086	A Phase 1/2 Trial of the Synthetic Cannabinoid ART27.13 in Patients with Cancer Anorexia and Weight Loss	Prof. Andrew Davies	Our Lady's Hospice & Care Services	Artelo Bioscience Limited	22/09/2021	Favourable
21-NREC-CT-095	Multi-centre, double-blind, randomised placebo-controlled, phase IIa trial to evaluate spesolimab (BI 655130) efficacy in patients with fibrostenotic Crohn's Disease	Prof. Laurence Egan	University Hospital Galway	Boehringer Ingelheim	06/10/2021	Favourable

NREC Reference ID	Study title	National Principal Investigator	Institution	Sponsor	Meeting date	Final decision
21-NREC-CT-100	A Phase 3, Randomized, Double-blind, Controlled Study Evaluating the Efficacy and Safety of VX-121 Combination Therapy in Subjects With Cystic Fibrosis Who Are Homozygous for F508del, Heterozygous for F508del and a Gating (F/G) or Residual Function (F/RF) Mutation, or Have At Least 1 Other Triple Combination Responsive CFTR Mutation and No F508del Mutation	Prof. Edward McKone	St. Vincent's University Hospital	Vertex Pharmaceuticals Incorporated	06/10/2021	Favourable
21-NREC-CT-101	A Phase 3, Randomized, Double-blind, Controlled Study Evaluating the Efficacy and Safety of VX-121 Combination Therapy in Subjects With Cystic Fibrosis Who Are Heterozygous for F508del and a Minimal Function Mutation (F/MF)	Prof. Edward McKone	St. Vincent's University Hospital	Vertex Pharmaceuticals Incorporated	06/10/2021	Favourable
21-NREC-CT-120	A phase II study to evaluate the long-term safety and efficacy of alpelisib in patients with PIK3CA-Related Overgrowth Spectrum (PROS) who previously participated in Study CBYL719F12002 (EPIK-P1)	Prof. Alan Irvine	Our Lady's Children's Hospital	Novartis Pharma AG	17/11/2021	Favourable
21-NREC-CT-127	Protocol IM026024: A Phase 2, Multicenter, Randomized, Double-blind, Placebo-Controlled, Study to Evaluate the Efficacy and Safety of BMS-986256 in Participants with Active Systemic Lupus Erythematosus	Dr Trevor Duffy	Connolly Hospital	Bristol Myers Squibb International Corporation	03/11/2021	Favourable
21-NREC-CT-129	HORIZON: A phase II, open-label, outcomes-assessor masked, multicentre, randomised, controlled study to evaluate the safety and efficacy of two doses of GT005 administered as a single subretinal injection in subjects with geographic atrophy secondary to dry age-related macular degeneration	Dr Eugene Ng	UPMC Whitfield Hospital	Gyroscope Therapeutics	03/11/2021	Favourable

NREC Reference ID	Study title	National Principal Investigator	Institution	Sponsor	Meeting date	Final decision
21-NREC-CT-130	Phase II, randomized, open-label, international, multicenter study to compare efficacy of standard chemotherapy vs. letrozole plus abemaciclib as neoadjuvant therapy in HR-positive/HER2-negative high/ intermediate risk breast cancer patients. "CARABELA Study"	Prof. Catherine Kelly	Mater Misericordiae University Hospital	GEICAM	03/11/2021	Favourable
21-NREC-CT-131	A Multicenter, Randomized, Double-Blind, Parallel-Group Study to Assess the Efficacy and Safety of Oral Etrasimod as Induction and Maintenance Therapy for Moderately to Severely Active Crohn's Disease	Prof. Gerard Clarke	Portiuncula University Hospital	Arena Pharmaceuticals, Inc.	03/11/2021	Favourable
21-NREC-CT-132	A Phase 3 Open-Label, Randomized Study of Pirtobrutinib (LOXO-305) versus Bendamustine plus Rituximab in Untreated Patients with Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (BRUIN-CLL-313)	Dr Anne Fortune	Mater Misericordiae University Hospital	Loxo Oncology, Inc.	03/11/2021	Favourable
21-NREC-CT-133	An Open-label, Randomized Phase 3 Study to Evaluate Efficacy and Safety of Pembrolizumab (MK-3475) in Combination with Belzutifan (MK-6482) and Lenvatinib (MK-7902), or MK-1308A in Combination with Lenvatinib, versus Pembrolizumab and Lenvatinib, as First-line Treatment in Participants with Advanced Clear Cell Renal Cell Carcinoma (ccRCC)	Prof. Sean Raymond McDermott	Tallaght University Hospital	Merck Sharp & Dohme Corp	17/11/2021	Favourable
21-NREC-CT-134	A Phase 3, Randomized, Double-Blind Study of Pembrolizumab versus Placebo in Combination With Paclitaxel With or Without Bevacizumab for the Treatment of Platinum-resistant Recurrent Ovarian Cancer (KEYNOTE-B96 / ENGOT-ov65)	Dr Dearbhaile Collins	Cork University Hospital	Merck Sharp & Dohme Corp	17/11/2021	Favourable

Appendix II.

Overview of applications for new studies reviewed by NREC-MD in 2021

NREC Reference ID	Study title	National Principal Investigator	Institution	Sponsor	Meeting date	Final decision
21-NREC-MD-001	PORSAV (Protecting OR Staff from Aerosolized Virus)	Prof. Ronan Cahill	Mater Misericordiae University Hospital	Palliare	27/05/2021	Favourable
21-NREC-MD-003	Non-inferiority of angiography-derived physiology guidance versus usual care in an All-comers population treated with unrestricted use of Healing-Targeted Supreme stent (HT Supreme) and P2Y12 inhibitor monotherapy after 1-month of dual-antiplatelet therapy: The PIONEER IV trial	Prof. Patrick Serruys	National University of Ireland, Galway	National University of Ireland, Galway	24/06/2021	Favourable
21-NREC-MD-004	MyopiaX Treatment for the Reduction of Myopia Progression in Children and Adolescents: Safety and Efficacy Investigation	Prof. James Loughman	Technological University Dublin	Dopavision GmbH	24/06/2021	Favourable
21-NREC-MD-005	Conduction System Pacing Optimized Therapy (CSPOT)	Dr Jonathan Lyne	Beacon Hospital	Medtronic Bakken Research Center BV	29/07/2021	Favourable
21-NREC-MD-009	A prospective, multicenter post-marketing clinical investigation of the Tsert SITM System, model NG SI IMT 3X in patients with central vision impairment associated with end-stage age-related macular degeneration	Prof. David Keegan	Mater Misericordiae University Hospital	VisionCare Ophthalmic Technologies Ltd	26/08/2021	Favourable

NREC Reference ID	Study title	National Principal Investigator	Institution	Sponsor	Meeting date	Final decision
21-NREC-MD-010	LANDMARK Trial: A prospective, multinational, multicentre, open-label, randomized, noninferiority trial to compare safety and effectiveness of Meril's Myval Transcatheter Heart Valve (THV) series vs. Contemporary Valves (Edwards' Sapien THV series and Medtronic's Evolut THV series) in patients with severe symptomatic native aortic valve stenosis	Dr Darren Mylotte	Galway University Hospital	Meril Life Sciences Pvt. Ltd.	30/09/2021	Unfavourable
21-NREC-MD-011	An observational study of ocular microtremor in mild head injury	Prof. Geraldine McMahon	St James's Hospital	Trinity College Dublin	30/09/2021	Favourable
21-NREC-MD-013	Real-World Outcomes Study on Subjects Treated with Radiofrequency Ablation	Dr Paul Murphy	St. Vincent's University Hospital	Abbott	28/10/2021	Withdrawn
21-NREC-MD-014	Randomised, single dose, crossover, open label, placebo controlled, single site confirmatory clinical investigation in patients with gastro-oesophageal reflux, to characterise the acid neutralisation activity of a calcite chewing gum, using oesophageal ambulatory pH monitoring	Dr Martin Buckley	Mercy University Hospital	Reckitt Benckiser Healthcare UK	25/11/2021	Favourable
21-NREC-MD-015	Fractional Flow Reserve or 3D-Quantitative-Coronary-Angiography Based Vessel-FFR guided revascularization	Prof. Robert A. Byrne	Mater Private Hospital	European Cardiovascular Research Institute (ECRI)	25/11/2021	Favourable

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