Health Research Board
NCTO
National Clinical Trials Office

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Newsletter Autumn, 2023

Dear Colleagues,

A warm welcome to the Autumn edition of our Newsletter and I hope you and your loved ones got to enjoy some very well-deserved downtime over the Summer period. I don't know about you, but it certainly seemed to have whizzed by!

Yet again, we've a bumper edition and we're considering moving to a more frequent cycle, as resources allow. Please do keep feeding in any material you want to communicate to the wider clinical research community in Ireland to ncto@ucc.ie and we'll be happy to help promote here and on our social media channels. Do give us a follow on our X (aka Twitter) and LinkedIn pages too.

Just to highlight a few specific areas that might be of interest;

Communication about the great work ongoing in our sector is really important, so it's great to see that Cancer Trials Ireland have a fabulous podcast series aimed both at the professional and lay communities and available on all player formats.

If you're involved, interested or likely to want to connect in with the MedTech sector, supported by Irish MedTech Skillnet and the Irish Medtech Association, we've a great workshop coming up on October 12th.

This edition we're focusing a spotlight on the great work being undertaken in the Infectious Disease Trial Network. This network focuses on bringing innovation to the ever evolving national and international challenges of Infectious disease control.

Last but not least, we are using this edition to highlight the great work of our colleague Evelyn Crowley. Data, intelligence and insight are key to the activities and efficiencies of health research and in this piece, Evelyn outlines the utility of the CRF-Manager software which is available to all clinical research facilities in our partnership.

Wishing you every success.

Rob
Robert O'Connor Ph.D

HRB Health Research Board

UCC
University College Cork, Ireland
Coláiste na hOllscoile Corcaigh

Enterprise Ireland

HRB NCTO Medtech Workshop

Event: Clinical Investigations & Performance Studies in Ireland under the MDR/IVDR

Where: 84/86 Lower Baggot Street Dublin 2

When: 12th October 2023 (10:00 - 16:30)

This will be a practical guide, workshop and networking event for those conducting or planning a Clinical Investigation of a Medical Device in Ireland.

Supported by **Irish Medtech Association** and **Irish Medtech Skillnet**, this workshop is led by the **Clinical Industry Liaison Officer** of the **Health Research Board National Clinical Trials Office.**

This in-person event is free of charge and will provide an overview of how to prepare for and execute a clinical investigation of a medical device under the MDR and IVDR in Ireland.

Dates for your Diary

HRB-TMRN's Winter School, Galway, 19 Oct 2023

HRB-TMRN's 8th Trials Methodology Symposium, Galway, 20 Oct 2023

Irish Health Research Forum ,Dublin, 16 Nov 2023

IRNM Conference, Limerick, 16 Nov 2023

NREC & HRB, National Conference on Research Ethics, Dublin, 30 Nov 2023

Medtech Rising, Galway, 7 Dec 2023

If you would like your event featured here in future newsletters, email ncto@ucc.ie and we will be happy to accommodate.

The workshop will include a series of presentations from guest speakers as well as ample time for questions and answers and networking.

Organisations represented will include

- Health Products Regulatory Authority (HPRA)
- National Research Ethics Committee for Clinical Investigations of Medical Devices and Performance Studies of In Vitro Diagnostic Medical Devices (NREC-MD)
- HRB National Clinical Trials Office (NCTO)
- Irish Medtech Association
- Irish Medtech Skillnet

The NCTO and guest speakers will give their expert advice and be ready to answer questions from the audience.

Speakers from Medtech companies who have successfully carried out clinical investigations in Ireland for regulatory approval in EU and USA will share their experience using case studies. We are delighted to announce that Andrea Sauerland, Vice President Clinical Operations, Endotronix will share her experience of conducting clinical investigations of a Class III cardiovascular device in Ireland and EU.

To book your space at the workshop, please **click here**

NCTO Website News

We are delighted to announce the revamp of the Medtech pages of the NCTO website. Now you can find all you need to know about performing a medical device clinical investigation in Ireland. Please check it out here.

For even further Medtech information, you can download our Medtech Toolkit which has information on everything from the Medical Device Regulations (MDR), how to engage with the HPRA and all you need to know about Software as a Medical Device. Click here to register and download the Toolkit.

Infectious Diseases
Clinical Trial Network Profile

The **Infectious Diseases Clinical Trials Network Ireland** (ID-CTNI) brings together leading academic clinicians and researchers in Infectious Diseases across Ireland to support trials to meet future health threats. ID-CTNI is currently focused on studies in COVID-19, HIV and Mpox areas, but future prospects across further areas within the field of Infectious Diseases are anticipated. ID-CTNI is led by Prof Paddy Mallon, at University College Dublin and St Vincent's University Hospital, and is managed by Polina Smolovyk. The ID-CTNI is funded by the HRB for five years commencing on 1st of December 2021.

The ID-CTNI is hosted by the UCD Centre for Experimental Pathogen Host Research (CEPHR) (**link to website**) and involves 5 partner hospitals: St Vincent's University Hospital, Mater Misericordiae University Hospital, St James's Hospital, Beaumont Hospital, Cork University Hospital. Also participating directly with ID-CTNI trial activities are HIV Ireland, as a partner NGO, and University Hospital Galway, as a collaborating institution.

A Community Advisory Board (CAB) made up of PPI representatives is a key component of the ID-CTNI to ensure the patient voice is integrated into all core Network activities. The CAB oversees and advises on all PPI activities within the Network and will be represented on ID-CTN Steering Committees. PPI members were invited to the European HIV Seminars organised by CEPHR on June 16th-17th 2023 to further develop the collaborative activities.

Community Advisory Board with Prof Mallon at European HIV Seminars 2023

An International Advisory Board, made up of senior, international Infectious Diseases Academics and Trialist, is also integral to the ID-CTNI structure. The IAB provides advice and feedback on research strategy, informing the strategic direction of future ID-CTNI activities.

The objectives of the ID-CTNI are:

- Establish and implement a governance structure, together with existing CRCs and Biobanking facilities, that improves quality, coordination and methodology in Infectious Diseases research in Ireland.
- Fully integrate existing investigator-initiated clinical trials into the ID-CTNI and expand recruitment to other network sites.
- Conceive, implement, complete and report three, collaborative, multicentre clinical trials within the lifetime of the award.
- Ensure that the patient perspective is embedded in clinical trial design, development and delivery.
- Provide research programs that provide a training ground for future clinical trialists.
- Demonstrate sustainability by attracting funding.
- Leverage the Network's global interconnectivity to expand ID-CTNI developed protocols to international collaborator sites and to make collaborator trials available to Irish patients.
- Integrate ID-CTNI activities with other Irish CTNs and strategic initiatives in Infectious Diseases in Ireland (e.g. Biobanking and National Research Centres initiatives) and internationally to enable a rapid and effective pandemic response.

CRFManager®

CRFManager® Support Services

The HRB National Clinical Trials Office (NCTO) oversees all aspects of CRF Manager for its user network in Ireland. The NCTO maintains a dedicated email account for CRF Manager inquiries (**crf-manager@ucc.ie**). In addition, the NCTO has direct access to the developers of CRF Manager for all technical support needs.

Evelyn Crowley acts as the HRB NCTO's Data Analyst and manages CRF Manager for the local user network.

Evelyn Crowley, Data Analyst, HRB NCTO

What is CRFManager®?

CRFManager® is a web-based resource management system primarily employed for the management of clinical research studies and various aspects of facility operations. CRFManager® was developed by the University of Edinburgh in 2005 and is widely used throughout the UK & Ireland. Currently, CRFManager® is utilised by 7 large University-affiliated Clinical Research Facilities across Ireland.

The system assists in the management of various aspects of clinical research studies, including scheduling visits, recording study information, tracking study progress and managing study documentation. In addition, CRFManager® can be used for day-to-day aspects of facility management. This may include scheduling resource usage (i.e., room bookings), tracking equipment utilisation and managing personnel.

Being web-based means that users can access CRFManager® from anywhere with an internet connection, providing flexibility and remote access.

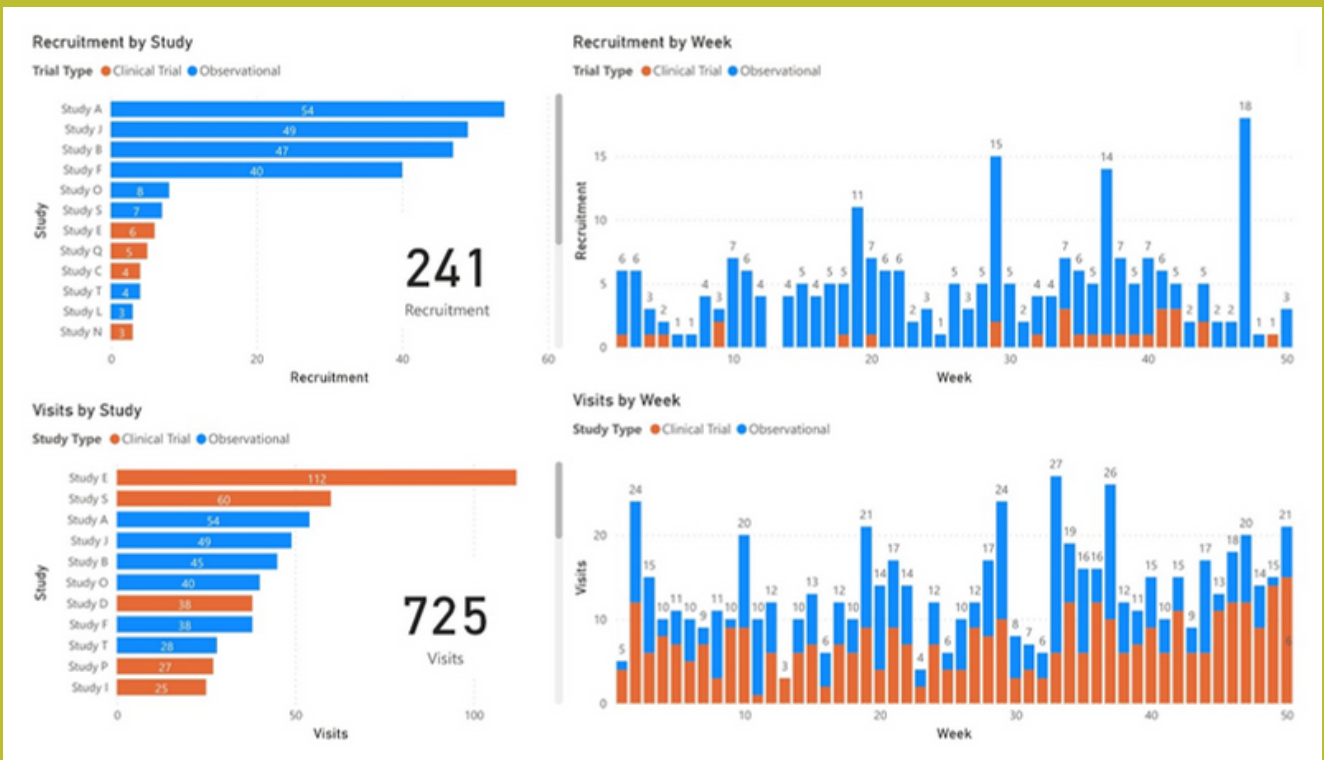
CRFManager®

CRFManager® Stats

From 1st January to 30th August 2023, NCTO handled a total of 276 CRFManager® queries. These queries encompassed a wide range of topics, including but not limited to, user account configuration and modification, password recovery, study initiation and administration, resource management, as well as support requests for the provision of training and reporting.

Power BI Reports

In the NCTO we have harnessed the capabilities of PowerBI to generate interactive dashboards aimed at illustrating study performance and resource management. Utilising the reports that are available on CRF Manager, we can create custom dashboards for individual sites depending on their requirements.
Below is an example of a Power BI report (anonymised) that was created for a site to illustrate patient visit and recruitment data across the facility for 2022.



ECRIN Updates

The **ERA4Health Partnership** "Fostering a European Research Area for Health", aims to bolster Europe's position at the forefront of science and innovation in Health Research by 2050 by creating a funding body for joint programming in priority areas addressing European public health needs and effectively establishing coordination between most funding organisations in the ERA.

A major aspiration of the **ERA4HEALTH** partnership is to provide a funding mechanism for multinational Investigator-Initiated Clinical Studies (IICS) across Europe by enabling European investigators to plan and design large, statistically powered clinical trials conducted throughout Europe. As part of this process, a Literature Review was developed by ECRIN colleagues from NorCRIN and HRB NCTO focusing on the Bottlenecks to the planning and conduct of multicountry IICS.

Niall Hore (HRB NCTO), as the ECRIN European Correspondent for Ireland, was the co-task leader on the ERA4Health Literature Review Deliverable and presented his results along with his Norwegian colleagues at an ERA4Health Partnership Workshop titled *'Analysis of the Bottlenecks and Challenges in Designing and Conducting Multicountry Investigator Initiated Clinical Studies'*.

Niall Hore, Irish EuCO presenting at ERA4Helalth workshop in Paris, September 2023

ECRIN Updates

The two-day Workshop took place in Paris from September 14th to 15th and was attended by representatives from ERA4Health, ECRIN, the European Commission, and Sponsors and Funders from throughout Europe.

The theme for Day 1 of the Workshop was on why IICS are fundamental to research and began with a presentation from Niall Hore and his colleague that highlighted the barriers and associated bottlenecks to IICS planning identified via the results of their Literature Review. Their presentation was then followed by an interactive session where attendees were invited to participate and provide instant feedback on related questions via the online platform SLIDO with the results to be included in the final report. Topics covered in this session included the added value and need for IICS, the barriers with the largest impact and realistic solution-orientated approaches.

ECRIN Updates

The evening portion of the event was dedicated to hearing different perspectives from Investigators, Academic Sponsors, Regulators and Funders which concluded with a round table discussion with panellists and questions from the audience. Ireland was well represented in this session as along with Niall Hore presenting on his ERA4Health Deliverable, Oonagh Ward from the HRB gave insight on funding clinical studies in Ireland and the infrastructures in place.

The theme for Day 2 of the Workshop was the challenges associated with new trial methodologies for clinical trials with complex designs, trials within cohorts, decentralized trials and IRB/EC approval challenges. Again, an interactive session using the SLIDO app allowed for the experienced attendees to provide instant feedback on queries relating to the advantages of innovative/complex designs, how can adaptive platform trials align with funding mechanisms and what type of studies will benefit from the implementation of these designs.

The workshop then concluded with another panel session that covered the topics discussed over the two days of the workshop, and also insight from European Commission representatives on the future of European funding for clinical studies.

Takeaways from the meeting included the importance of funding flexibility, patient engagement with the ever-changing landscape and new trial designs, and the continued need for harmonisation efforts throughout Europe aligning with the introduction of CTIS.

Have you been listening?

THE Cancer Trials Ireland PODCAST

Season 2
Out Now
Check out this podcast **here**

Ecosystem Updates

ICH-GCP is currently being updated to Revision 3

Why? Since last revision in 2017 there have been huge changes in complexity of trials and trial design (Basket trials, cluster trials, platform trials etc), use of technology (e-Consenting, e-TMF, data collection of patient data via smart phone etc)

What? Recurring themes include Proportionality and Risk Based Approach, Emphasis on reliability of data. R3 uses more pragmatic language and approaches (e.g., requirements around use of licensed Drugs as IMP). Principles reduced from 13 to 11, new section on data governance, updates to ensure Decentralised trials can be accommodated (e.g remote monitoring, use of e-Consenting)

When? Open for public consultation in EU until 26 Sept 2023. Due to be adopted June/July 2024.

Want to know more?
database.ich.org/sites/default/files/ICH_E6%28R3%29_Guideline_GCP_Video_2023_0601.mp4 (short video)

ICH Official web site: https://ich.org/page/efficacy-guidelines

Have you been watching?

Documentary series following the lives of the families, babies, and staff in the busy newborn intensive care unit in Cork University Maternity Hospital.

Watch on Virgin Media One and/or Virgin Media Player

Patient Registries

Health Research Charities Ireland (HRCI) & their collaborators **National & International Skin Registry Solutions** (**NISR**) & **Cystic Fibrosis Registry of Ireland** (CFRI) have recently published the following report: **Unlocking the Potential of Patient Registries: A Guide for Success**. It lays out practical advice on developing & sustaining a patient registry.

The CFRI and HRCI co-hosted an event, entitled *The Future of Patient Registries in Ireland*, in February 2023. The aim of the event was to celebrate 20 years of collecting data by the CFRI and to share lessons learnt by existing registries at different phases of their evolution. Alongside this, the event aimed to consider the policy and standards context in which registries operate, and to facilitate discussion about patient registries in Ireland. Over 100 people attended the event, and the discussions have influenced this update of our earlier 2018 publication on this theme.

This publication expands the previous version by extending guidance beyond setting up a registry to operating and sustaining a registry and also seeks to reflect the changing data protection and technological environment. That said, this guide is not intended to be exhaustive or systematic, but rather a series of guiding principles and key points to help readers think through the process of developing, operating and sustaining a registry. It has been written with patient organisations and all with an interest in health data in mind.

The guide is structured into 3 main sections: developing a registry, operating a registry, and sustaining a registry, each with a number of sub-sections. The sections are not intended to reflect a stepwise process to be completed sequentially, rather a set of important areas readers should consider concurrently.

Reference: Unlocking the Potential of Patient Registries: A Guide for Success, 2023, HRCI/ NISR /CFRI, https://bit.ly/RegGuide2023

Upcoming Meetings

Data Management in Health Research - You're funded but are you ready to be FAIR?

Save the date! 25th October 2023, Creative Zone, UCC Library

Sonraí (Irish Data Stewardship Network) aims to develop and support data stewardship skills across the national research landscape through raising the profile data stewards, greater recognition of the need for data stewardship, professionalisation of the role of data steward, and knowledge dissemination throughout this emerging community. This symposium is part of a wider project funded by the National Open Research Forum aiming to identify and organise staff engaged in data stewardship through a series of national roadshows.

What does a Data Steward do?

While there is no universally agreed definition of data stewardship, there is a range of tasks and skills that form part of everyday research activities. These can include: research data management planning; metadata creation and application; database management; data curation and preservation; supporting Open Data and the FAIR principles; data infrastructure development and management; teaching and skills development for researchers; open research advocacy; and policy development. So a data steward supports many tasks associated with the overall research objectives of a project. These activities take place throughout the research lifecycle from planning the research, capturing the data, analysis, report dissemination, to post-project preservation and data sharing.

Who should attend?
On the 25th October, 'data stewards' working in health-focused research are invited to join the conversation. All major funders require engagement with FAIR data management practices. There is also an expectation that the data captured during the research is made 'as open as possible, yet as closed as necessary'. This is set against a backdrop of data protection rights on behalf of the patient and responsibilities on behalf of the researcher where explicit consent for the processing of those personal data must be outlined, obtained and adhered to.
Few job descriptions identify staff roles as 'data steward'. However, data stewardship responsibilities may informally account from 0.1 FTE and upwards in many instances. We encourage any staff therefore with job roles and responsibilities as outlined above to join us on the day.

Programme
The day will comprise of two sessions. In the morning, a national networking event for staff engaged in data stewardship will take place. An understanding of shared activities and roles will be developed which will feed into the establishment of a wider network of data stewards extending to all research disciplines.

The afternoon session will begin with a panel discussion including HSE, HRB and SFI representatives on their aspirations for researcher adoption of FAIR data management practices and the maturation of funder policy in the coming years. The day will conclude with invited speakers in the health research space outlining their experiences with respect to FAIR data management and the observed downstream benefits of the intersection between increased data quality and enhanced research integrity.

Registration for the symposium will open in September.

Contact Dr Brendan Palmer (b.palmer@ucc.ie) if you require further information.

EU CANCER MISSION DAY - IRELAND is a collaboration between the All-Island Cancer Research Institute (AICRI) and the National Cancer Control Programme (NCCP) through the ECHoS project. Bringing together academic researchers, clinician scientists and healthcare professionals, charity partners and policymakers, together with those with a lived experience of cancer, the event will share their insights, knowledge and experiences and explore innovative approaches to address cancer challenges.

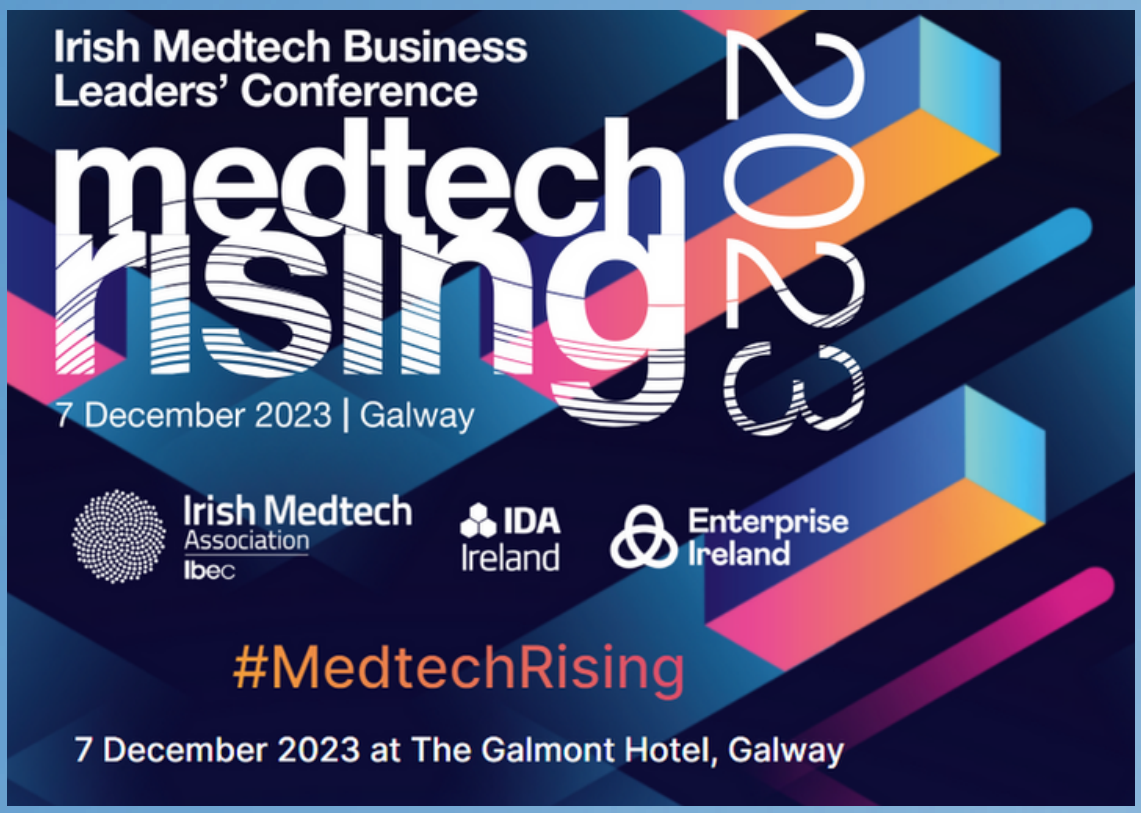
Registration Link and Agenda can be accessed via this link: https://www.eventbrite.ie/e/eu-cancer-mission-day-ireland-online-tickets-682109025457

IRNM 15th Annual National Conference

Where: Clinical Education and Research Centre, University Hospital Limerick

More Information: https://irnm.ie/event/conference/

Medtech Rising 2023



For More Information : https://www.ibec.ie/connect-and-learn/events/upcoming-events/2023/medtech-rising-2023/general-details

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Health Services Research and Pharmacy Practice (HSRPP) Conference 2024

Conference theme: Sustainable Development in Healthcare

When: 25 – 26 April 2024
Where: University College Cork, Cork, Ireland
Website: https://www.ucc.ie/en/hsrpp2024/

Funding Schemes

Emerging Clinician Scientist Awards (ECSA) 2024

The Emerging Clinician Scientist Awards (**ECSA**) scheme supports talented health and social care practitioners who are engaged in research, who can make a valuable contribution to knowledge in health research, and who are capable of becoming independent and self-directed investigators.

The **Health Research Board** (HRB) is specifically seeking individuals who are passionate about the application of knowledge in improving healthcare systems, policies, or practice.

The **ECSA** scheme will use a two-stage application process consisting of:

1. An open call for Pre-applications (Stage 1) – HRB deadline 23-Nov-2023.
2. Invitation of selected applicants to submit a Full Application (Stage 2) – opens Late-January 2024 with Full Application closing Late-March 2024

The overarching aim of the HRB ECSA is to develop a cohort of new and talented health and social care practitioners of any professional background in the Republic of Ireland by facilitating and supporting their transition towards research independence in line with the research career path for health and social care practitioners.

For further details on this award scheme, **click here**

Investigator-Led Projects (ILP) 2024

The ILP scheme aims to support highly innovative and internationally competitive investigator-led projects that can respond to existing and emerging challenges for health and social care.

For more information, **click here**

Emerging Investigator Awards (EIA) 2024

The Emerging Investigator Awards (EIA) scheme supports talented individuals who can make a valuable contribution to knowledge in health research and who are capable of becoming independent and self-directed investigators. The Health Research Board (HRB) is specifically seeking individuals who are passionate about the application of knowledge in improving healthcare systems, policies, or practice.

For more information, **click here**

SFI Research Centres Programme

Science Foundation Ireland have launched the **2023 SFI Research Centres Programme Call.**

This new programme builds on its success over the past decade and has been informed by extensive consultation with various groups including Government, the public sector, industry, and the higher education and research system. The goal is to develop a dynamic, cohesive and streamlined ecosystem of internationally renowned Research Centres, marked by scientific excellence and underpinned by the bringing together of a critical mass expertise for collaborations of scale to yield national and international impact.

In partnership with industry, government and civil society, Centres will develop talent and provide innovative solutions to Ireland's economic, societal and environmental challenges. Deep and impactful public engagement will be integrated into the fabric and culture of the Centres to bring significant value to the research, the researchers and all those working in the Centre, and to deliver benefit for public good. The programme is open to applications that align with the National Research Priority Areas 2018-2023 and SFI's remit.

For more information on this call, **click here**

REG & ETHICS

Accelerating Clinical Trials in the European Union (ACT EU) initiative will support smarter clinical trials through regulatory, technological and process innovation.

ECRIN

SAVE THE DATE - ECRIN CTU day is happening on 4th December (10:00-13:00H CET).
Online event with more details to follow .

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