Ensures patients in Ireland have prompt access to new and developing innovative therapies
There is now widespread acceptance that IPPOSI has an important leadership role in the area of medicine development.

2012 was an important year in the development of IPPOSI. It was a year in which our organisation delivered a strong diary of events and developed policy in a number of key areas. It was also the first year of our 2012 – 2015 strategic plan, which was developed in consultation with members. The plan has assisted the staff of IPPOSI to plan the organisation’s activities in a focused and effective manner to deliver the strategic priorities set out in the plan.

Our work in the areas of clinical research, rare diseases, access to new treatments and biobanking has had a positive impact on the sector in Ireland. IPPOSI is increasingly considered by decision makers as the principal point of contact for consulting with key stakeholders in these key policy areas. This point was best made at our recent Roundtable meeting on compliance and adherence when Dr Ambrose McLoughlin, Secretary General of the Department of Health highlighted the important leadership role of IPPOSI and its members stating that we “ensure patients’ interests are put first.” He stated that “the Department of Health will maintain very close links with IPPOSI, so that as we move forward, the Department will benefit from its input into policy making and evaluation”.

As predicted the changing healthcare environment and reduced budgets heavily influenced our activities and discussions in 2012 and 2013. At the 2012 IPPOSI Roundtable meeting, Access to Medicine, we played a pivotal role in bridging the gap between patients, science, industry and the decision makers in the Department of Health and elsewhere. It is our intention to continue that work in 2013 and beyond.

The passing of the Health Information Bill will be an important step for all those engaged in health information and in particular for patient registries. IPPOSI had previously published the IPPOSI/MRCG 2011 report entitled A National Strategy for Patient Registries – Considerations for Government. With the final wording of the bill being drafted, IPPOSI and MRCG again partnered in 2012 to hold a legislative update at which the Department of Health briefed members of both organisations on the likely contents of the Bill. The meeting highlighted that while the bill has been in development for many years, there are still many issues which will need to be debated once the final draft is published. IPPOSI expects to hold another meeting at that time. The recent announcement by Dr Ambrose McLoughlin that the Bill will be published in October is very welcome. As a non-lobbying organization it will be our intention to provide expert information and to facilitate a discussion between patients, science and industry on this legislative change.
Eibhlín Mulroe, CEO of IPPOSI is continuing her work as a member of the Department of Health’s Rare Diseases Steering Group which will conclude its workings 2013, the point at which all EU member states will be compelled by a council recommendation to produce a national plan for rare diseases. The all-Ireland conference, Rare Disorders Without Borders and the Farmleigh consultation on a Rare Disease Strategy were two important events in the development of a National Strategy and IPPOSI was pleased to provide logistical and event planning support along with the support of our industry members.

Finally I would like to acknowledge the support we have received from the Health Research Board. I also thank the staff of IPPOSI for their hard work and commitment during the year. I would like to express my appreciation to my colleagues on the board for their contribution to our work and to the shared goal of improving Irish patients’ access to new treatments and therapies. Dr Ruth Barrington retired from her role as director in 2012 and her support over the years has been invaluable. A special thanks to Ms Margaret Webb for her dedication to IPPOSI as Chairperson in 2012; Ms Webb retired earlier this year and we send her best wishes for the future.

Godfrey Fletcher

GOVERNANCE

The Board of IPPOSI consists of elected members from each of the participant sectors. Patient organisations are represented by eight members, with science and industry members each having six seats.

The Chairperson is always a representative from a patients’ organisation.

The Board of Directors
The Board of Directors of IPPOSI met 5 times in 2012. The Board manages and oversees the organisation and where it should focus its efforts in order to achieve goals and objectives. The Board is responsible for major decisions on spending, year on year. IPPOSI Directors will continue to develop and grow the Board ensuring there is a rotation of 1/3 of the Board every year according to our Memorandum and Articles of Association. While membership of IPPOSI is open to all those with an interest, the current Directors from each of the three sectors will also work to identify appropriate targets for membership.

Finance Committee
The Finance Committee is a subcommittee of the Board and is made up of the Chairperson, Treasurer and Secretary of the Board. The Committee interacts with the CEO on matters relating to financial management, staff remuneration and other HR issues. A full record of our financial information as of the 31st December 2012 is available in this report.
<table>
<thead>
<tr>
<th>IPPOSI Board Members 2012</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mr Godfrey Fletcher</strong></td>
<td>Cystic Fibrosis</td>
<td>Chairperson, IPPOSI</td>
</tr>
<tr>
<td><strong>Mr Philip Watt</strong></td>
<td>The Cystic Fibrosis</td>
<td>Association of Ireland</td>
</tr>
<tr>
<td><strong>Dr Tomás Carroll</strong></td>
<td>Alpha One</td>
<td></td>
</tr>
<tr>
<td><strong>Mr Jimmy Fearon</strong></td>
<td>Debra Ireland</td>
<td></td>
</tr>
<tr>
<td><strong>Ms Gina Plunkett</strong></td>
<td>Irish Chronic Pain</td>
<td>Association</td>
</tr>
<tr>
<td><strong>Ms Avril Daly</strong></td>
<td>Fighting Blindness</td>
<td></td>
</tr>
<tr>
<td><strong>Mr John McCormack</strong></td>
<td>Irish Cancer Society</td>
<td></td>
</tr>
<tr>
<td><strong>Ms Margaret Webb</strong></td>
<td>Raynaud’s and Scleroderma Ireland</td>
<td></td>
</tr>
<tr>
<td><strong>Dr Fergus O’Ferrall</strong></td>
<td>Trinity College Dublin</td>
<td></td>
</tr>
<tr>
<td><strong>Prof Seamas Donnelly</strong></td>
<td>UCD</td>
<td></td>
</tr>
<tr>
<td><strong>Dr Amanda McCann</strong></td>
<td>UCD</td>
<td></td>
</tr>
<tr>
<td><strong>Prof Colm O’Morain</strong></td>
<td>AMNCH and Trinity College Dublin</td>
<td></td>
</tr>
<tr>
<td><strong>Prof Brendan Buckley</strong></td>
<td>Irish Medicines Board</td>
<td></td>
</tr>
<tr>
<td><strong>Dr Ruth Barrington</strong></td>
<td>Molecular Medicine Ireland (retired September 2012)</td>
<td></td>
</tr>
<tr>
<td><strong>Ms Ciara O’Rourke</strong></td>
<td>MSD Ireland (Human Health)</td>
<td></td>
</tr>
<tr>
<td><strong>Ms Nicola Watt</strong></td>
<td>Alexion</td>
<td></td>
</tr>
<tr>
<td><strong>Mr Fred Doherty</strong></td>
<td>Genzyme</td>
<td></td>
</tr>
<tr>
<td><strong>Ms Sinead Duffy</strong></td>
<td>Bayer</td>
<td></td>
</tr>
<tr>
<td><strong>Dr Stephen McDonough</strong></td>
<td>GSK</td>
<td></td>
</tr>
<tr>
<td><strong>Ms Siobhan Gaynor</strong></td>
<td>Molecular Medicine Ireland (co-opted September 2012)</td>
<td></td>
</tr>
<tr>
<td><strong>Dr Velichk Valcheva</strong></td>
<td>Sanofi (retired 2012)</td>
<td></td>
</tr>
</tbody>
</table>
A STRONG START

CEO Eibhlín Mulroe

In 2012 IPPOSI completed a strategic planning process which will assist in planning the organisation’s activity for

The Board of IPPOSI and the CEO, in consultation with a management consultant began the strategic planning exercise in early 2012. The Board completed a questionnaire exercise followed by workshops outlining the key areas of priority for IPPOSI going forward. This work was then revisited by the wider membership and the final strategic priorities, objectives and actions were presented by the CEO to the Board in May 2012.

The strategic plan restates IPPOSI’s vision of ensuring patients in Ireland have prompt access to new and developing innovative therapies and defines the organisation’s mission as expediting the development of and patient access to innovative therapies through a unique partnership of patient groups, science and industry.

The plan identifies four strategic priorities to:

- Bring a patient perspective to clinical research
- Actively influence policy that impacts on research and access to innovative therapies
- Increase awareness and understanding of the work done by IPPOSI
- Source funding to ensure IPPOSI’s sustainability

I am pleased to report that since its publication, we have made progress in each of the areas that are strategically important to IPPOSI’s mission.

During the planning process and also through our recent interaction with the Innovative Medicines Development (IMI) project, the European Patient Academy for Therapeutic Innovation (EUPATI), it has become clear that the unique partnership of patients, science and industry has provided a perspective that is valued by key stakeholders in Ireland and across the EU. IPPOSI is seen as a model of best practice for collaboration between the three stakeholder groups at a European level. Through the IMI EUPATI consortium, the benefits of IPPOSI’s involvement in this project will evolve.

EUPATI emerged from the acknowledgement that patients across the EU want and need more information on the medicines development pathway. This innovative patient-led academy plans to develop and publish educational material, training courses and a public Internet library to educate patient representatives and the lay public about all processes involved in medicines development. IPPOSI’s takes the lead in Taskforce 2.3 for Work Package Two (WP2) in the EUPATI project which will build a strong EU-wide network of stakeholders to enable optimal knowledge-sharing and expertise on all six topics of interest. The funding received by this project allowed IPPOSI in 2012 to take on extra resources through the Communications Executive role to relieve the added work load.

We expect to be in a position to announce more exciting developments in 2013.

Eibhlín Mulroe
## STRATEGIC PLAN 2012 - 2015

### STRATEGIC PRIORITIES

<table>
<thead>
<tr>
<th>Bring a patient’s perspective to clinical research in Ireland</th>
<th>Actively influence policy that impacts on research and access to innovative therapies</th>
<th>Increase awareness and understanding of the work done by IPPOSI</th>
<th>Source funding to ensure IPPOSI’s sustainability</th>
</tr>
</thead>
</table>

### STRATEGIC OBJECTIVES

| • Develop a society where there is increased understanding and support for clinical research | • Participate in the development of a national strategy on rare diseases | • Engage members (existing and prospective) and develop an active membership base | • Maintain current funding and grow new sources of funding in Ireland and Europe |
| • Bring a patient perspective to the development of clinical research infrastructure | • Participate in the development of a national strategy and framework for biobanking and patient registries | • Establish IPPOSI as an expert group with the media outlets | • Develop a funding strategy to source future funding |
| • Facilitate stakeholders to develop a national strategy for biobanking and patient registries | • Bring increased transparency to the decision making process around access to innovative therapies | • Increase members understanding of the challenges around the development of and access to innovative therapies | |
| • Influence policy on health care system reform where it impacts on the work of IPPOSI. | |
| | | | |
Minister Reilly with Margaret Whelan, IPPOSI member
Members of the Rare Disease Steering Group: John McCormack, Helen McAvoy, Eibhlin Mulroe, Avril Daly and Tony Heffernan with the Minister for Health James Reilly at the 2012 DOH Consultation
IPPOSI builds consensus through bringing stakeholders together at major meetings or consultations.

The Board of IPPOSI envisages that the changing healthcare environment and reduced budgets will continue to influence the key activities and discussions within IPPOSI in the future. Further to discussions with key leaders in the Department of Health, IPPOSI expects to play a pivotal role in bridging the gap between patients, science and industry and the decision makers.

The office of IPPOSI has become the go-to for members and policymakers to connect with disparate stakeholders in a complex health environment on a variety of issues relating to development of and access to new medicines and treatments and engagement of patients in health policy development. The office is also a useful advice and information facility for members to gain knowledge on recent initiatives/debate or to get linked into Patient Organisations, Industry or Science members in their particular field. IPPOSI plays a pivotal role in bridging the gap between patients, science and industry and the decision makers. IPPOSI provides the patients’ perspective on Advisory Boards and Committees set up by HSE, HIQA, DOH, IMB and Universities.

IPPOSI has been successful in building on partnerships with key patient groups and other actors involved in Rare Diseases in Ireland and Europe. Since 2008, IPPOSI has partnered with the Genetic and Rare Disorders Group and the Medical Research Charities Group to effectively drive the Rare Disease Policy Agenda. IPPOSI reports and materials have been drawn upon by a variety of stakeholders to enhance understanding of rare diseases and the challenges they present to the key stakeholders. IPPOSI receives requests from rare disease patients looking for reliable information and has endeavoured to assist in this regard by providing information and by linking individuals with groups and entities that can help. IPPOSI continues to add to and promote a patient video channel.

The CEO of IPPOSI was appointed by the Minister of Health to the DOH Steering Group on Rare Diseases. All member states in the EU are compelled by a council recommendation to produce National Plans for Rare Diseases. IPPOSI will continue to link in with the Clinical Director in the HSE and the CMO’s Office in the Department of Health in this regard. The work will continue in 2013.

The Health Information Bill is an important step for all those engaged in health information and in particular the patient registry debate. IPPOSI has widely promoted the recommendations of the IPPOSI/MRCG 2011 document.
entitled; ‘National Strategy for Patient Registries – considerations for government’. It has also organised communication activities for members during 2012.

**Some key activities in 2012**

- **UCD/IPPOSI Module for 3rd year medical students on Rare Diseases.** The 20-week Rare Disease Module organised by Dr. Paula Byrne where patients and scientists lecture students on a variety of Rare Diseases. It took place in 2012 and a poster was presented to describe the course at the Annual Eurordis meeting.

- **Update on Forthcoming Legislation information meeting** dealt with the research aspects of the Health Information Bill and the Human Tissue Bill. An outcome report from this event will be circulated to all IPPOSI members.

- **Clinical Research for Non-Clinical Researchers** training facilitated by Molecular Medicine Ireland in 2012. The course was open to members and aimed to inform non-clinical researchers about the drug development pathway and the clinical trial process. Participants also explored the issue of consent and the international context of the Declaration of Helsinki and EU Directives.

- **Health Technology Assessment training** took place in the autumn of 2012 and addressed principles of pharmacoeconomics and the methodology used in the HTA process in Ireland, data sources used and the criteria applied when reaching decisions along with other European systems of assessment and the involvement

**Clinical Trials Training Day by Siobhan Gaynor, MMI**

**HTA Training Day: Prof Michael Barry, NCPE; Eibhlín Mulroe, IPPOSI; Nicola Bedlington, EPF; Margaret Webb, IPPOSI and Ralf Zimmerman, Bayer.**
of patients in these HTA processes. Prof Michael Barry asked in 2012 that the patient voice would be included in the HTA process and IPPOSI would be the link with the relevant patient organisations.

- **Access to Innovation meeting & Outcome Report** meeting was held in 2012 in response to reports of treatments which had been approved for reimbursement but were not reaching patients. IPPOSI asked key patient organisations to outline the issues and clarify the situation for their patient members. Outcome report was developed and launched in 2012.

- **IPPOSI and MRCG** held an event entitled; “An Update on Forthcoming Legislation”, a members’ information meeting which dealt with the research aspects of the Health Information Bill and the Human Tissue Bill, key pieces of legislation which will be published in 2012/2013. The measures contained in these bills will impact the health research environment in Ireland and are expected to contain new policy initiatives in the areas of population health registers, the structure and regulation of research ethics approval and regulations for the removal, retention, storage, use and disposal of human tissue.

- **IPPOSI invited the Irish Pharmaceutical Healthcare Association** to present to members on “Patients’ Organisations and the Code of Marketing Practice for the Pharmaceutical Industry” in 2012, the information day was enlightening for many members and will be repeated in 2013.

**Appointments in 2012**

- CEO of IPPOSI was appointed to the HIQA Advisory Board on Research Ethics in 2011 and this formed part of the work plan in 2012.
• CEO was appointed to the GSK Healthcare Media Award Judging Panel and subsequently spoke at the ceremony to the gathered healthcare media. Topics covered included: Patient perspectives on Access to Clinical Trials, Rare Diseases and Access to Medicines.

• CEO appointed to UCD SSRA Poster Adjudication Panel in 2012

• The CEO has also been appointed to the Consultative Forum on Legal Classification of Medicinal Products at the Irish Medicine’s Board.

Bringing a Patient Perspective to clinical research in Ireland (2012) - Clinical Trials

One of the many IPPOSI Information Days in 2012 focused on clinical research in order to inform non-clinical researchers about the clinical research process. Participants received an introduction to clinical research and an explanation of the terminology and conventions used.

In August RTE Broadcaster Aine Lawlor launched a new IPPOSI information campaign ‘clinicaltrials.ie’ which aimed to answer many of the questions which people may have if they are asked to participate in a clinical trial. The campaign was made up of a new leaflet and a dedicated website, two sources of information which will provide patients with independent answers to many of the questions which they may have. From the research which IPPOSI has undertaken, we know that providing information increases the positive attitude which people have about participating in a clinical trial. Increasing the willingness of people to participate in such research will inevitably increase Ireland’s capacity to conduct high-quality clinical research and thus help to develop new treatments and therapies for patients. The event was widely covered in the media.

Following the success of the clinicaltrials.ie campaign, IPPOSI and the National Children’s Research Centre, Crumlin have partnered to develop a guide for children taking part in clinical trials. The guide is aimed at both the child and their guardians. IPPOSI are also seeking other partners to develop similar information campaigns regarding clinical research.
Partnership with Industry and Decision Makers

UK Deputy Prime Minister, Nick Clegg, MP, came to University College Dublin to meet with academics, researchers, patient organisations and individuals taking part in studies led by the university in 2012. Nick Clegg was accompanied by the Minister for Enterprise, Jobs and Innovation, Richard Bruton, TD, and the President of UCD, Dr Hugh Brady. The three met with IPPOSI alongside Dr Stephen McDonough, GSK. IPPOSI was represented by CEO, Eibhlin Mulroe and Directors, Prof. Seamas Donnelly and Ms Margaret Webb. IPPOSI presented our report on Public Attitudes to Clinical Research and the need to better inform the public of the value of an enriched clinical research environment.

Increase awareness and understanding of the work done by IPPOSI (2012)

In 2012 a Communications Officer was appointed to assist in disseminating the work of IPPOSI and provide valuable information on key initiatives to a wider audience.

Requests for inclusion in the IPPOSI e-communication mailing lists continue to steadily increase as does the readership of IPPOSI newsletters and EAlerts. IPPOSI has received sizeable feedback on the value and quality of these communications and how these have enabled organisations to inform/enhance their own activity. In addition, IPPOSI is using social media (linkedin and twitter) as a medium to communicate with members and channel weekly updates.

IPPOSI CEO participated in media interviews in 2012 on a variety of topics including public attitudes to clinical research, access to medicines, Health Technology Assessments and Rare Disease policy in Ireland. In addition, she has been a member of the judging panel for the GSK Healthcare Media Awards since 2009 and this has provided opportunities to profile IPPOSI.

IPPOSI is a member of the HSE Service User Group, DOH Steering Group on Rare Diseases, Rare Disease Task Force, HIQA Advisory Board on HTA and Research Ethics and IMB Consultative Forum on Legal Classification of Medicinal Products.

Eibhlin Mulroe, IPPOSI presents in Frankfurt to European patient representatives as Chair of Taskforce 2.3 in the European Patients’ Academy for Therapeutic Innovation (EUPATI) project.
Income and Expenditure Account
for the year ended 31 December 2012

<table>
<thead>
<tr>
<th>Notes</th>
<th>Income</th>
<th>Expenditure</th>
<th>(Deficit)/Surplus on ordinary activities before interest</th>
<th>Other interest receivable and similar income</th>
<th>(Deficit)/Surplus on ordinary activities before taxation</th>
<th>Tax on (Deficit)/Surplus on ordinary activities</th>
<th>(Deficit)/Retained surplus for the year</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>116,815</td>
<td>(177,682)</td>
<td>(60,867)</td>
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<td>199</td>
<td>37,522</td>
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<td>37,522</td>
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</table>

A separate Statement of Total Recognised Gains and Losses is not required as there are no gains or losses other than those reflected in the profit and loss account.

### Balance Sheet
as at 31 December 2012

<table>
<thead>
<tr>
<th>Notes</th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fixed Assets</td>
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<td>€</td>
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<tr>
<td>Tangible assets</td>
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<td>-</td>
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<tr>
<td>Current Assets</td>
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<td>99</td>
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<tr>
<td>Debtors</td>
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<tr>
<td>Cash at bank and in hand</td>
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<tr>
<td>Creditors: amounts falling due within one year</td>
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<td>(42,825)</td>
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<tr>
<td>Net current assets</td>
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<td>51,090</td>
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<tr>
<td>Total assets less current liabilities</td>
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<td>51,679</td>
</tr>
<tr>
<td>Net assets</td>
<td></td>
<td>51,679</td>
</tr>
<tr>
<td>Reserves</td>
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<tr>
<td>Revenue reserves account</td>
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<td>51,679</td>
</tr>
<tr>
<td>Members’ funds</td>
<td>11</td>
<td>51,679</td>
</tr>
</tbody>
</table>
IPPSI Finance Committee: Sinead Duffy, Margaret Webb, Godfrey Fletcher with Eibhlin Mulroe, CEO.
MEMBERSHIP 2012

The IPPOSI membership is made up of patients’ organisations, individuals from the scientific and research community and Industry members.

Patients’ Organisations:
22q11 Support Group Ireland
Alpha One
Alzheimers Society of Ireland
Ankylosing Spondylitis Association of Ireland (ASAI)
Arthritis Ireland
Bee For Battens, The Saoirse Foundation
Cystic Fibrosis Association of Ireland
Cystic Fibrosis Registry of Ireland
Cystinosis Foundation of Ireland
DEBRA Ireland
Dercum Disease Patient
Diabetes Action
Diabetes Federation of Ireland
Duchenne Ireland
Ehlers Danlos Syndrome
EPOS
Fabry Ireland
Federation of European Scleroderma Associations
Fighting Blindness
Friedreich’s Ataxia Society Ireland
Genetic & Rare Disorders Organisation (GRDO)
Hospice Foundation
Huntington’s Disease Association of Ireland
Ileostomy & Internal Pouch Support Group
IMD Action Group
Irish Cancer Society
Irish Fragile X Society
Irish Haemophilia Society
Irish Kidney Association
Irish Lupus Society
Irish ME/CFS Association
Irish Motor Neurone Disease Association (IMNDA)
Irish Osteoporosis Society
Irish Premature Babies
Irish Sarcoidosis Support Network (ISARC)
Irish Society for Mucopolysaccharide Diseases MPS
MPS Society
Medical Research Charities Group (MRCG)
Multiple System Atrophy (MSA)
Muscular Dystrophy Society of Ireland Ltd
Myasthenia Gravis Association
National Adult Literacy Agency (NALA)
OvaCare
Parkinson’s Association of Ireland
Prader-Willi Syndrome Association (PWSAI)
Raynaud’s & Scleroderma Ireland
Rett Syndrome Association of Ireland

Industry:
Abbott
Alexion
Bayer
BioMarin
Celgene
Genzyme
GSK
Janssen-Cilag
MSD
Novartis Ireland Limited
Pfizer
Sanofi
Shire Pharmaceuticals Ltd
Individual science and research members from:

Beaumont Hospital
Belfast City Hospital
Biobank Ireland Trust
Childrens University & Mater Hospitals & UCD
Clinical Research Centre Beaumont Hospital
CSTAR
Department of Public Health, HSE - Southern Area
Dr Steevens Hospital
Dublin Dental School & Hospital
EMA Paediatric Committee
HSE South - Department of Public Health
Mater University Hospital - National Pulmonary Hypertension Unit
Mater University Hospital
Midland Regional Hospital
Molecular Medicine Ireland
National Centre for Pharmaeconomics - St, James
National Children’s Research Centre (NCRC)
National Cancer Registry (NCRI)
NUI Galway
OHCAR - the National Out-of-Hospital Cardiac Arrest Register
Our Lady’s Childrens Hospital Crumlin (OLCHC)
Oncology Clinical Trials Cork University
Perinatal Ireland
Royal College of Surgeons Ireland (RCSI)
Regional Immunology Service The Belfast Trust
Research Foundation, Royal Victoria Eye & Ear Hosp.
Royal Victoria Eye & Ear Hospital
School of Health Sciences
Science Foundation Ireland (SFI)
Science Foundation Ireland (SFI) - Discover Science & Engineering
St. James Hospital
St. Vincent’s University Hospital
TCD
TCD/Adelaide & Meath Hospital
TCD - School of Nursing & Midwifery
The Children's Medical & Research Foundation (CMRF)
The Mater Foundation
The Research Foundation Royal Victoria Eye & Ear Hosp.
Tril - Technology Research for Independent Living
UCD
UCD Clinical Research Centre St. Vincent’s Hospital
UCD Conway Institute
UCD Medical Genetics Research Group
UCD Research
UCD School of Law
UCD School of Medicine and Medical Science