

PDA / IMB
ESOF2012 Satellite Conference

Making Gene and Cell Therapy Medicines a Reality

*An Effective Partnership
between Authorities and Industry*

July 10-11, 2012, Dublin, Ireland



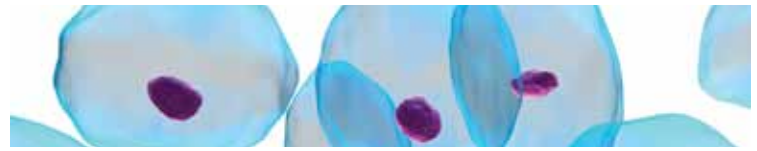
**ESOF2012
DUBLIN**



IRISH MEDICINES BOARD



PDA
Parenteral Drug Association
Ireland Chapter



The meeting is on the theme of "Making Gene and Cell Therapy Medicines a Reality". It is being jointly organized by the Parenteral Drug Association (PDA) and the Irish Medicines Board (IMB) in a first time association. The meeting will also be a satellite event to a major European scientific event in Dublin: The EuroScience Open Forum or, ESOF2012.

The focus of the meeting will be very much on outlining the regulatory framework and challenges of translating the exciting basic science

discoveries related to molecular and cell biology into novel, commercial gene and cellular therapies. It aims to bring together leading experts from Regulatory Agencies like the European Medicines Agency (EMA) and the US Food & Drug Administration (FDA) with expert academic and industrial scientists in this area for a fruitful interaction. It also aims to ensure that representatives of patients and those with an ultimate need for these products will be actively included in the meeting in line with an aim of ESOF2012 to bring science to the public.

July 10, 2012 DAY 1

VENUE: Gibson Hotel, Dublin

Opening / Introduction

Dr Frank Hallinan, PDA, Chair of Conference

Morning Session:

Chair: TBD

This Session will Focus on the Science of Cell and Gene Therapy and the Odyssey to Bring these Products to the Patient

Cell Therapy: From White Cells to Stem Cells

Prof Frank Barry, REMEDI

Gene Therapy: Packaging Nucleic Acids to get them in!

Prof Caitriona O'Driscoll, UCC

Break

Gene Therapy in the Clinic - the CF Odyssey

Prof Gerry McElvanney, RCSI

Gene Therapy and RP – A long standing Goal

Prof Jane Farrar, Genable & TCD

Cell Therapy for Cancer – The Irish Odyssey

Dr Patrick J Hayden, St James Hospital

Advanced Therapies - The Patient Perspective

Dr Michele Lipucci Di Paola, EURORDIS

Cell Therapy – An Industry Perspective

Drs Ron Fedechko & Tricia Harbinson, Pfizer

LUNCH

Afternoon Session:

Chair: Dr Frank Hallinan, PDA

This session will Focus on the Requirements to make and Treat Patients with these Products

The Irish National Cell Therapy Facility

REMEDI Speaker Invited

The UK Stem Cell Bank

NIBSC Speaker Invited

Starting up a commercial GMP Gene Therapy Facility

Oxford Biomedica Speaker Invited

The Oxford Clinical BioMfg Facility

Dr Eleanor Berrie, University Oxford, Clinical Biomanufacturing Facility

Break

Ark Therapeutics Manufacturing Gene Therapy Products

Ark Speaker Invited

Comparison of Large Scale GMP Culture of Mammalian cells for Cell Therapies and Protein Biotherapeutics

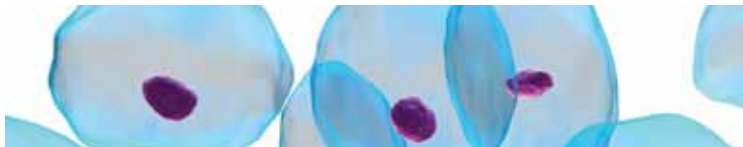
Mr Sean Cullen, Geron Invited

The Amsterdam Molecular Therapeutics Experience

Dr Andrew Bakker, AMT

Close of Day 1





July 11, 2012 DAY 2

VENUE: Gibson Hotel, Dublin

Morning Session:

This Session will Focus on the Regulatory Requirements for Advanced Therapy Medicinal Products in the EU and USA.

Chair: Dr Mike Morris, IMB

Introduction to Meeting

Dr Mike Morris, IMB &
Member of European Pharmacopoeia Commission

Introduction to EU Regulation 1394/2007

Dr Maura O'Donovan, IMB & Member of CAT,
EMA

Challenges with Advanced Therapies from the EU regulatory
Perspective

Dr Christian Schneider
Danish Medicines Agency & Chair of CAT

US Regulation (Title TBD)

FDA Speaker Invited

Q&A led by Mike Morris

Break

Mid Morning Session:

This Session will Focus on IMB Regulatory Procedures for Advanced Therapy Medicinal Products.

Chair: Dr. Christian Schneider, CAT

The Authorisation of Hospital Exempt Manufacturers

Dr Patrick Costello, IMB

Hospital Exemptions: IMB policy and experience to date

Dr Sarah O'Meara, IMB & Member of CAT EMA

Clinical trial applications – IMB procedure & experience

Dr Una Moore, IMB & Member of
Biologics Working Party EMA

Harmonisation of the assessment of multi national Clinical Trials

Dr Agnieszka Przybyszewska, IMB & Member of
Clinical Trials Facilitation Group EMA

EMA and CAT support to Developers of ATMPs

Dr Patrick Celis, EMA & Secretariat to CAT

Q&A led by Christian Schneider

Lunch

Afternoon Session:

This Session will Focus on the Technical Aspects of Applications for ATMPs

Chair:TBD

Gene therapy products for Clinical Trials
- Advice on data requirements

Dr Matthias Renner, Paul Ehrlich Institute &
member of Gene Therapy Working Party

Cell-based medicinal products for Clinical Trials
- Advice on data requirements

Dr Paula Salmikangas, Finnish Medicines Agency
& Chair of Cell Based Working Party & vice-chair
of CAT

Limbal Stem Cells progress to date

Dr Sandra Shaw, IBTS

Topic of choice - progress to date

Prof Martin Clynes, DCU invited

Tissue engineering scaffolds for cell and gene delivery

Prof Fergal O' Brien, RCSI

Q&A led by Chair of Session

Closing Remarks to the Conference

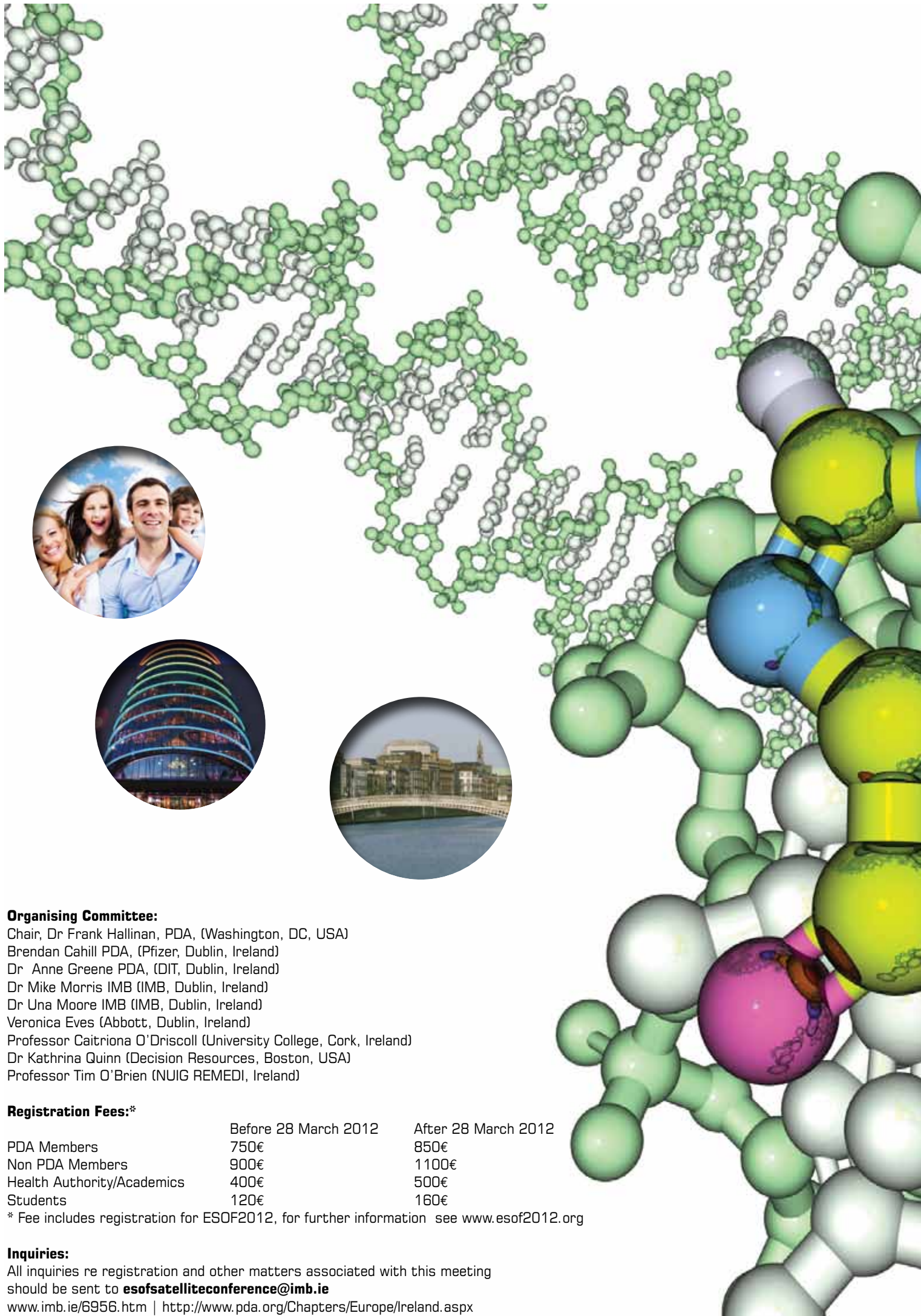
Brendan Cahill, Chair PDA Ireland

End of conference & Transfer to ESOF Meeting



IRISH MEDICINES BOARD





Organising Committee:

Chair, Dr Frank Hallinan, PDA, (Washington, DC, USA)
 Brendan Cahill PDA, (Pfizer, Dublin, Ireland)
 Dr Anne Greene PDA, (DIT, Dublin, Ireland)
 Dr Mike Morris IMB (IMB, Dublin, Ireland)
 Dr Una Moore IMB (IMB, Dublin, Ireland)
 Veronica Eves (Abbott, Dublin, Ireland)
 Professor Caitriona O'Driscoll (University College, Cork, Ireland)
 Dr Kathrina Quinn (Decision Resources, Boston, USA)
 Professor Tim O'Brien (NUIG REMEDI, Ireland)

Registration Fees:*

	Before 28 March 2012	After 28 March 2012
PDA Members	750€	850€
Non PDA Members	900€	1100€
Health Authority/Academics	400€	500€
Students	120€	160€

* Fee includes registration for ESOF2012, for further information see www.esof2012.org

Inquiries:

All inquiries re registration and other matters associated with this meeting should be sent to esofsatelliteconference@imb.ie
www.imb.ie/6956.htm | <http://www.pda.org/Chapters/Europe/Ireland.aspx>