



ETTORE MAJORANA FOUNDATION AND CENTRE FOR SCIENTIFIC CULTURE

TO PAY A PERMANENT TRIBUTE TO GALILEO GALILEI, FOUNDER OF MODERN SCIENCE
AND TO ENRICO FERMI, "THE ITALIAN NAVIGATOR", FATHER OF THE WEAK FORCES



INTERNATIONAL SCHOOL OF PHARMACOLOGY "GIAMPAOLO VELO"

DIRECTORS: M. LINDQUIST, P. MINUZ, U. MORETTI

IMPROVING THE DETECTION, ANALYSIS AND REPORTING OF HARMS IN MEDICINES

Exploring, Enhancing and Empowering in Erice (4Es Forum)

Erice, Sicily, 6th (arrival) - 10th (departure) October 2019

Workshop Directors : M. Lindquist, R. Chandler, C. Heneghan, R. Leone

1. **Explore** the problems with regulatory approvals of medicines
2. **Enhance** the assessment and reporting of harms in medicines
3. **Empower** the next generation of solutions for approvals of safer medicines

Current approval of medicines is failing to detect the signals of harms within the evidence-base. Problems within the regulatory system have often led to the approval of ineffective and harmful drugs. Postmarketing is largely ineffective in detecting problems once a drug is on the market. New solutions to address these problems are needed. Finding solutions, however, to better detect, analyse and report harms will not be straightforward. Advance the detection and reporting/safety signals for medicines is critical to providing better healthcare for all.

We are planning a three-day workshop on the tasks ahead to provide solutions for better detection, analysis and reporting of harms.

We are inviting individuals with expertise and/or experience in:

- Pharmacovigilance
- Drug regulation and,
- the reporting and communicating of medicine harms

We are also including the next generation of problem solvers to contribute to the solutions which will go far into the future.



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PROGRAMME:

Sunday, 06 th October 2019 : Arrival		
	Arrival of participants and check-in at the Ettore Majorana Foundation.	

Monday, 07 th October 2019 : Pre-marking approvals		
08:30 - 09:00	Registration & coffee	
09:00 - 09:30	Welcome & introductions Carl and Marie open to discuss the purpose, aims and achievements for the meeting	
09:30 - 11:00	Identify problems with pre-marking approvals Chair: Rebecca Chandler 1A - Asger Sand Paludan-Muller 1B - 1C - Peter Gotzsche	3 x 20 min: presentations 30 min: Q&A / discussion
11:00 - 11:30	Coffee	
11:30 - 13:00	Group Workshop 1: Brainstorm on the problems	Facilitated by AM speakers
13:00 - 14:00	Lunch	
14:00 - 15:30	Identify potential solutions to the problems of pre-marking approvals Chair: Robin Ferner 2A - Tom Jefferson 2B - Catherine Riva 2C - Jeff Aronson	3 x 20 min: presentations 30 min: Q&A / discussion
15:30 - 16:00	Coffee	
16:00 - 17:30	Workshop 2: Brainstorm on potential solutions	Facilitated by PM speakers
17:30 - 18:30	Sum up / overview of the day Chair: Carl Heneghan A, B, C nominated spokesperson	

Secretariat of the Centre: Via Guarnotta 26 - 91016 Erice, Italy - Tel. 0923 869133 - Fax 0923 869226 - E-mail: hq@ccsem.infn.it

Secretariat of the School: Dipartimento di Diagnostica e Sanità Pubblica, Sezione di Farmacologia, Università di Verona
Policlinico "G.B. Rossi" - P.le L. Scuro, 10 - 37134 Verona, Italy - E-mail: isphav@ateneo.univr.it - Website: www.isphav.org



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Tuesday, 08 th October 2019: Post-licensing		
09:00 - 10:30	Identify problems with post-licensing Chair: Jamie Coleman 3A - Gilles Mignot 3B - Florence Van Hunsel 3C - Joan-Ramon Laporte	3 x 20 min: presentations 30 min: Q&A / discussion
10:30 - 11:00	Coffee	
11:00 - 12:30	Workshop 3: Brainstorm on the problems	Facilitated by AM speakers
12:30 - 14:00	Lunch	
14:00 - 15:30	Identify potential solutions to post-licensing problems Chair: Saad Shakir 4A - Mick Foy 4B - Luca Li Bassi 4C - David Healy	3 x 20 min: presentations 30 min: Q&A / discussion
15:30 - 16:00	Coffee	
16:00 - 17:30	Workshop 4: Brainstorm on potential solutions	Facilitated by PM speakers
17:30 - 18.30	Sum up / overview of the day Chair: Marie Lindquist A, B, C nominated spokesperson	
19:30	Event dinner	

Wednesday, 09 th October 2019: Communication / dissemination to patients, the public, clinicians and regulators		
9:00 - 10:30	Identify the problems / barriers to communicating / disseminating in pharmacovigilance Chair: Helen McDonald 5A - 5B - Kath Sansom 5C - Faye Kirkland	3 x 20 min: presentations 30 min: Q&A / discussion
10:30 - 11:00	Coffee	

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11:00 - 12:30	Workshop 5: Brainstorm on the problems	Facilitated by AM speakers
12:30 - 14:00	Lunch	
14:00 - 15:30	Identify potential solutions to the problems of communication Chair: Kim Witczak 5A – Serena Tinari 5B – Anthony Cox 5C – Bruce Hugman	3 x 20 min: presentations 30 min: Q&A / discussion
15:30 - 16:30	Group reflections Chair: Carl Heneghan A, B, C nominated spokesperson. Discussion and next steps. Close: Marie Lindquist	

Thursday, 10th October 2019 :
Departure.

	Departure of participants.	
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PARTICIPANTS:

Rebecca Chandler
Jeff Aronson
Jamie Coleman
Anthony Cox
Nick De Vito
Kay Dickersin
Ivor Ralph Edwards
Robin Ferner
Mick Foy
Su Golder
Peter Gotzsche
David Healy
Carl Heneghan
Bruce Hugman
Tom Jefferson
Lars Jorgensen
Faye Kirkland

Joan-Ramon Laporte
Tianjing Li
Luca Li Bassi
Marie Lindquist
Helen MacDonald
Giles Mignot
Georgia Richards
Catherine Riva
Gerard Ross
Asger Sand Paludan-Muller
Kath Sansom
Daniele Sartori
Saad Shakir
Serena Tinari
Florence van Hunsel
Kim Witczak