BBS / PSI 1-Day Scientific Meeting: Empower the immune system to fight cancer

Thursday 15th June 2017, Roche IT Centre

Immunotherapy treatments use parts of a person's immune system to fight disease. In the recent past, immunotherapy has become an important part of treating some types of cancer e.g. melanoma, NSCLC. Studies of these treatments have resulted in a number of observations that have implications for the statistician e.g. delayed treatment effects, long term survivors etc. This joint Basel Biometric Society / PSI one day meeting will present an overview of the science and potential statistical challenges across a range of topics covering early and late phases of development, regulatory and health technology assessments. The speakers from Academia, Regulatory agencies, and Pharma will share their thoughts, ideas and experiences, including case studies. There will be plenty of time for questions and interactions with colleagues.

| 8:30 | Registration |
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| 9:00 | Welcome, Emanuela Pozzi, Roche |
| 9:10- 10:30 | The Science of Immunotherapy Dominik Heinzmann, Roche, chair |
| 9:15 | Realising the potential of cancer Immunotherapy Jorge Martinalbo, Roche |
| 10:00 | Statistical issues in the development of cancer Immunotherapy Andrew Stone, Stone Biostatistics |
| 10:30 | Tea and Coffee |
| 11:00- 12:10 | Early development challenges Emanuela Pozzi, Roche, chair |
| 11:00 | Bayesian Learning in Early Phase Cancer Immunotherapy: A Case Study Daniel Sabanés Bové, Roche |
| 11:30 | An adaptive phase II basket study design: a case study Matt Whiley, Novartis |
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12:00

Lunch





Venue

Kindly hosted by Roche:
IT Centre Auditorium - Building 655 –
Aeschenvorstadt, 56,
4051 Basel, CH
How to get there:
http://www.maths.qmul.ac.uk/~bb/POD
E/PODE2014_How_to_get_there.pdf

Registration

BBS/PSI Members: £140.00 (plus VAT) Non-Members: £200.00 (plus VAT) Academics: £70.00 (plus VAT)

YOU CAN NOW REGISTER AND PAY ONLINE AT www.psiweb.org

Contact:

PSI Secretariat: psi@mci-group.com Tel: +44 (0) 1730 715 235 Fax: +44 (0) 1730 715 291 Durford Mill, Petersfield, Hampshire GU31 5AZ

If an attendance certificate is needed, please contact the PSI Secretariat.

MEETING ABSTRACTS WILL BE POSTED ON www.psiweb.org

Many thanks to Roche for hosting the June event.

If you have any questions please contact one of the organisers from the BBS or PSI Scientific Committee:

david.lawrence@astrazeneca.com or dominik.heinzmann@roche.com or emanuela.pozzi@roche.com

If you would like to host a PSI one day meeting for a topic of particular interest to you, please contact:

mouna.akacha@novartis.com,

(PSI Scientific Chair)

| 13:00- 14:40 | Late development: Statistical and Regulatory challenges Alex Allepuz (Novartis), Emanuela Pozzi (Roche), co-chair | Suggestions for hotels: www.hotel-victoria-basel.ch/ (4****) |
|-----------------|---|---|
| 13:00 | Statistical, clinical and ethical considerations when minimizing confounding for overall survival in cancer immunotherapy trials Dominik Heinzmann, Roche | http://www.hoteleuler.ch/ (4****) |
| 13:25 | Challenges in development and approval: the case of cell based therapeutic Sergio Fracchia, Novartis | https://www.motel- one.com/en/hotels/basel/ (3***) |
| 13:50 | Development of Immunotherapies – challenges encountered at MHRA Yolanda Barbachano, MHRA (UK) | |
| 14:30 | Panel Discussion on Early and Late Phase All Speakers and Frank van den Ouweland (Swissmedic) | |
| 14:50 | Tea and Coffee | |
| 15:10- 16:15 | Beyond approval (HTA) Dominik Heinzmann (Roche), chair | |
| 15:10 | Cancer immunotherapy from the Health Technology Assessment (HTA) and payer perspective Fred Sorenson, Xcenda | |
| 15:35 | Estimating survival benefit for health technology assessment: new challenges presented by immuno-oncology treatments? Nick Latimer, University of Sheffield | |
| 16:00 | Discussion beyond approval | |
| 16:15 | Meeting end | |