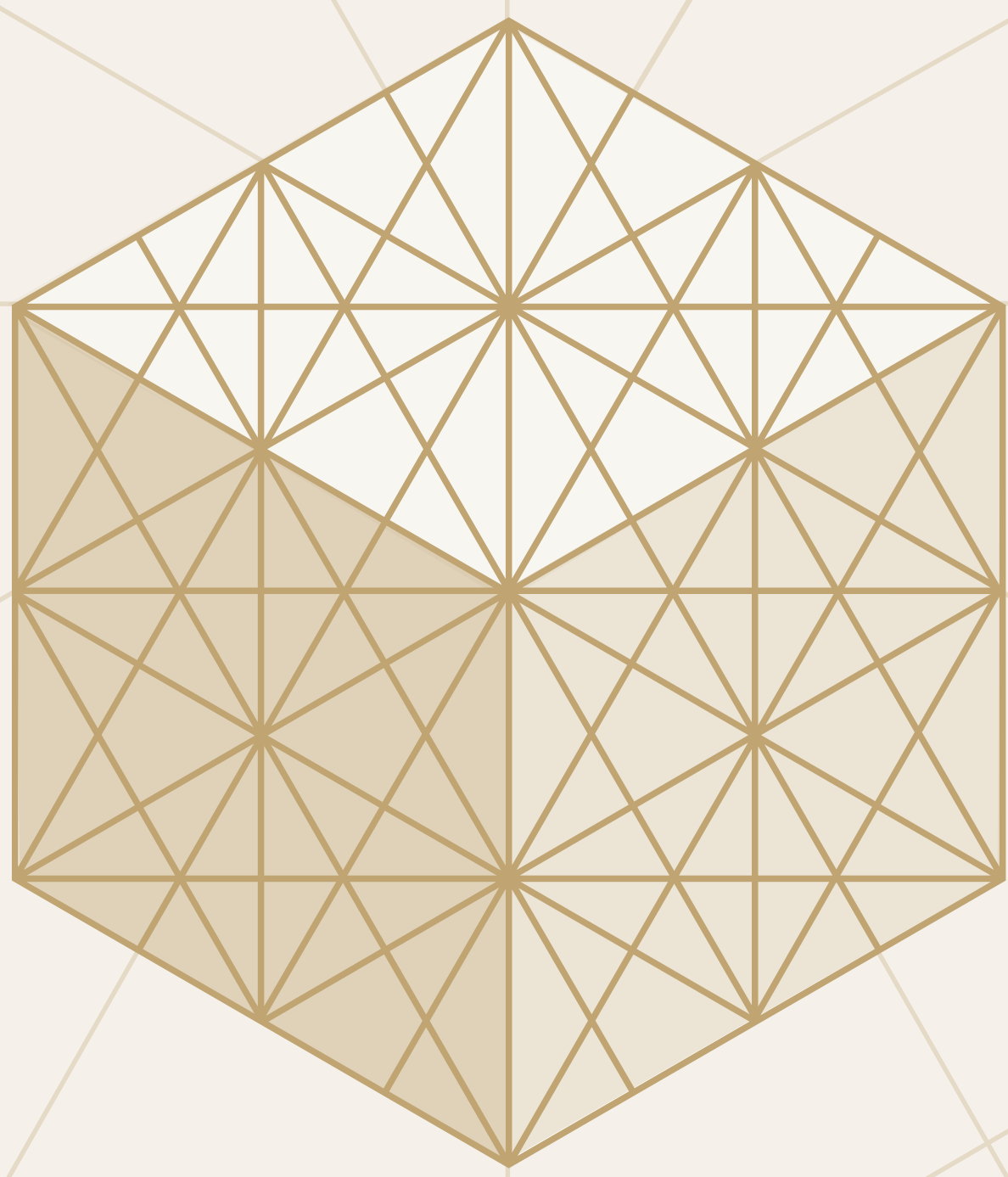


2019 SEMINARS



# RAMPS

Regulação e Avaliação do Medicamento e Produtos de Saúde

## 1<sup>st</sup> Part

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### 3<sup>rd</sup> May

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17h00 – 18h30

**Challenges for the Approval and Reimbursement of Anti-Cancer Immunotherapeutic Drugs**  
- Mira Pavlovic-Ganascia (NDA)

18h30 – 20h00

**The EUnetHTA Framework:** state of play, challenges and future goals  
- Rui Santos Ivo (ULisboa, INFARMED IP, EMA MB)

### 4<sup>th</sup> May

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9h00 – 10h30

**Biosimilars:** when a copy is not a copy  
- Fátima Ventura (ULisboa, INFARMED IP, CHMP Alternate Member)

10h30 – 12h00

**Challenges and Opportunities for Paediatric Drug Development**  
- Koenrad Norga (Vice-Chair of PDCO, CHMP Member, Leuven University / Belgium)

14h00 – 15h30

**Cardiovascular Outcome Trials:** a regulatory conundrum  
- Bart van der Schueren (Leuven University, Belgium / CHMP Member)

15h30 – 17h00

**Strengths and Weaknesses of the European Regulatory Framework:** perspectives from a stakeholder  
- Karsten Bruins-Slot (Roche, Norway; Former-CHMP Member Norway)

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**Registration at**  
**[www.ff.ulisboa.pt](http://www.ff.ulisboa.pt)**

