

INsTRuCT Workshop 3

March 20-21/2023 at Sanquin, Plesmanlaan 125, 1066 CX Amsterdam

Topic: Scientific Advice and Interacting with Competent Authorities

Workshop discussion leaders:



Dr. Anja ten Brinke
Sanquin Research and
Sanquin Diagnostics



Prof.dr. Marieke van Ham
Sanquin Research and
SILS, University of Amsterdam



Prof.dr. Eva Martínez Cáceres
Head of the Immunology Division
Germans Trias i Pujol University Hospital

Program Monday, March 20, Sanquin Room B-108

8.45-9.00: *arrival and coffee/tea*

9.00-9.15: *Introduction to the program of the workshop for Monday March 20*

Prof. dr. Marieke van Ham, Sanquin Research and Swammerdam Institute for Life Sciences,
University of Amsterdam

9.15-10.00: *35 minutes talk + 10 minutes discussion*



Presentation “Overview of the process and experiences with the EMA and other European authorities for new drugs and ATMPs”

Prof. dr. Ed Geissler, Head of Experimental Surgery, University Hospital Regensburg and Program Leader of the ONE study.

10.00-10.30: BREAK

10.30-11.15: *35 minutes talk + 10 minutes discussion*



Presentation “Successful regulatory applications and grounds for non-acceptance”

Prof. dr. Nathalie Cools, senior lead scientist of the Immune Regulation and tolerance-inducing Strategies (IRiS) research group, Faculty of Medicine and Health Sciences of the University of Antwerp and CEO of Anicells

11.30-12.00: Formulate 4 questions per break-out group for regulatory officials this afternoon in break-out rooms.

- Formulate 1 question for each of the officials of the afternoon
- People per break-out room and location:
 - Break-out room 1: 5 ESRs: Nathalie Cools Room: B-108, live
 - Break-out room 2: 5 ESRs: Eva Martinez-Caceres and Marieke van Ham, Room: B-201 live/online (room has LCD screen and a HDMI connection for Eva to join online meeting option)
 - Break-out room 3: 5 ESRs: Ed Geissler and Anja ten Brinke , B-204 live/online (room has LCD screen and a HDMI connection for Ed to join online meeting option)

ESR Christine Kreher made together with the other ESR the composition of the 3 ESR groups (based on mixing the ESRs across INsTRuCT WPs, so that each group contains ESRs with different levels of background on the topic):

Group 1 (with Nathalie)	Group 2 (with Eva/Marieke)	Group 3 (with Ed/Anja)
Zahra	Giulia	Konstantina
Ioana	Antonia	Alessia
Maaïke	Maria	Laura
Ayesha	Tomi	Federico
Jorge	Benjamin	Christine

12.00-13.00: LUNCH (get lunch in lunch canteen and stay there or move back to B-108)

13.00-13.35: 20 minutes talk + 15 minutes discussion (ESR ask group questions and discuss)



Presentation “Development Cellular ATMP’s - a trial-regulatory perspective: scientific, medical, societal, ethical”

Prof. dr. Joop van Gerven, neurologist/clinical pharmacologist at Leiden University Medical Centre, chairman of the Central Committee on Research Involving Human Subjects (CCMO)

13.35-14.10: 20 minutes talk + 15 minutes discussion (ESR ask group questions and discuss)



Presentation “Regulatory considerations for preclinical development of cell-based products”

Dr. Tineke van den Hoorn, Senior assessor Pharmacology, Toxicology and Biotechnology, Medicines Evaluation Board (College ter Beoordeling van Geneesmiddelen/CBG)

14.10-14.40: BREAK

14.40-15.15: 20 minutes talk + 15 minutes discussion (ESR ask group questions and discuss)



Presentation “Quality Considerations for Development of Cellular ATMP with a focus on safety and efficacy”

Dr. Marcel Hoefnagel, Senior Assessor Biopharmaceuticals of the Medicines Evaluation Board (College ter Beoordeling van Geneesmiddelen/CBG) and Chair Quality Innovation Group of the European Medicines Agency (EMA)

15.15-15.50: 20 minutes talk + 15 minutes discussion (ESR ask group questions and discuss)



Presentation “Testing of potency and safety, and monitoring of cellular therapeutics”

Prof. dr. Fred Falkenburg, professor in Experimental Haematology at Leiden University Medical Centre, chairman past of the Central Committee on Research Involving Human Subjects (CCMO)

15.50-16.20: BREAK

16.20-16.50:



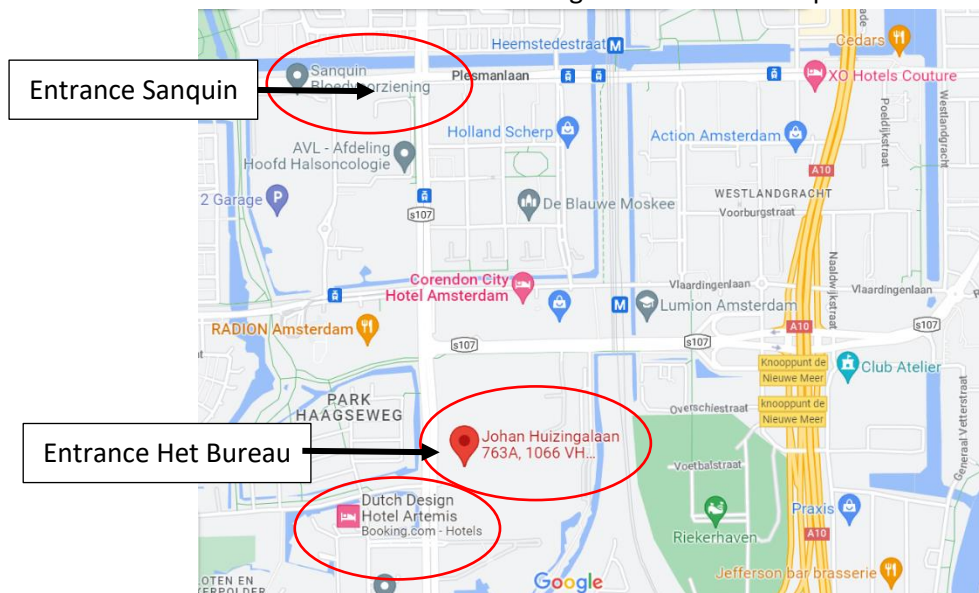
Presentation: A personal perspective: What to do and what to avoid in a biomedical career in terms of jobs, grants applications and generating networks.

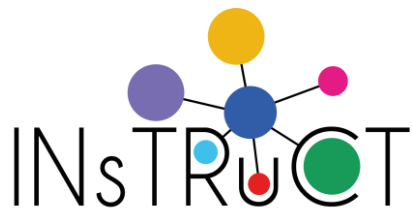
Prof. dr. Marieke van Ham, Sanquin Research and Swammerdam Institute for Life Sciences, University of Amsterdam

18.00: DINNER

Bar Bistro Bureau
5de verdieping van B. Amsterdam
Johan Huizingalaan 763a
1066 VH Amsterdam
Tel.: +31 (0)20 723 84 92

The restaurant is within 10 minutes of walking distance from Sanquin:





Program Tuesday, March 21, Sanquin Room B-209

8.45-9.00: Arrival and coffee/tea

9.00-9.15: Introduction to the program of the workshop for Tuesday March 21

Dr. Anja ten Brinke, Sanquin Research and Sanquin Diagnostics and Amsterdam University Medical Centre, University of Amsterdam

9.15-10.00: 35 minutes talk + 10 minutes discussion



Presentation: “Considerations for performing contract research in both a regulatory space and under research conditions”

Dr. Julian Freen-van Heeren, Sanquin Health Solutions: Immunomonitoring Services

10.00-10.15: BREAK

10.15-12.45:



Interactive workshop “Under INSTRUCOTion”; start of coaching and intervision trajectory of ESR.

dr. Jettie Muris; coach and trainer for professionals career paths (bio-)medical professionals

12.45: CLOSURE

Contact information in case of emergency:

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