

## GEMINI meeting 2

**Date: May 27<sup>th</sup> -28<sup>th</sup> 2024**

### Venue:

Room 2052 (Seminar room on 2<sup>nd</sup> floor)

Alice Perry Engineering Building

University of Galway

Google maps:

<https://www.google.com/maps/place/53%C2%B017'01.9%22N+9%C2%B003'47.9%22W/@53.2837965,-9.0645608,18.29z/data=!4m4!3m3!8m2!3d53.283863!4d-9.063303?entry=ttu>



## Program

**May 27<sup>th</sup>**

Time (local time!)		Presenter
9:00	<b>Welcome</b> - Sign-in - Refreshments -	
9:15	<b>Welcome</b> - Short recap of overall Perspective/detailed Project Vision - Explanation of agenda and aim	<b>Henk/Alfons</b>
9:30	Introduction partner (Bonn) lecture on ethics and humanities aspects (30', 15' questions)	<b>Matthias Braun</b>
10:30-10:35	welcome address by Professor Peter McHugh, Deputy President of Galway University.	<b>Peter McHugh</b>
10:35	<i>Coffee break</i>	
10:50	Short update from WP2-7, 15'presentation, 5'discussion	<b>ALL</b>
12:35-13:30	<i>Lunch</i>	
13:30-14:00	<b>Continued-updates</b>	
14:00-14:45	AI for device development and the Regulatory environment	<b>Neuravi Team*</b>
14:45-15:15	VV40 accreditation credibility	<b>Oscar</b>
15:15-15:30	<i>Coffee break</i>	
15:30- 16:15	Overview of data demands/requirements/storage Research management	<b>ALL /Henk</b>
16:15- 17:15	How to access data? -presentation of the two platforms where people can access data and images	<b>Philippe Bijlenga</b>
17:15- 17:30	Explanation on Contrast <a href="https://contrast-consortium.nl">Data requests (consortium members and trial collaborators) - contrast consortium (contrast-consortium.nl)</a>	<b>Charles</b>

17.30 Closure

19.00 Drinks and Dinner (Kirby's of Cross Street, 3/5 Cross Street Upper, Galway H91 DV52,

Phone Number (091) 569 404

## **\* The Neuravi Team:**

### **Mairsíl Claffey**

*Mairsíl has held diverse leadership roles encompassing Quality, Regulatory and Clinical in both start-ups and corporates. Over the course of her 33-year career, Mairsíl has guided Venture Capital funded start-ups, created QA/RA departments, designed and led clinical trials for novel products, and successfully obtained regulatory approval of assorted products, including Abbott Vascular's EmboShield, and JnJ's, EmboTrap.*

*Mairsíl currently works as a Clinical Director of Science and board member for Cerenovus, Neurvai Ltd. (subsidiary of JnJ MedTech).*

### **Shauna Devery**

*Shauna Devery holds a Bachelor's degree in commerce, with a specialization in Digital Business & Analytics, and a Master of Science in Business Analytics. Currently working as a Regulatory Affairs Associate, Shauna leverages a strong foundation in analytics and business strategy to navigate and ensure compliance with the regulatory landscape. Her expertise in data analytics and artificial intelligence, developed during her Master's program, is particularly useful in her current role working as part of the team on the in silico project.*

### **Marie Seoighe**

*Marie is a Senior Regulatory Affairs Specialist at Cerenovus. In her role, Marie has responsibility for Regulatory strategies and has submitted Regulatory filings with the FDA and EU notified bodies and supports global product submissions. She completed a Bachelor (BSc) of Applied Biology and Biopharmaceutical Science from the Atlantic Technological University (ATU) in Galway, Ireland. She then completed a Higher Diploma in Science in Medical Technology and Regulatory Affairs also with ATU with focus on the EU MDR, Regulatory fundamentals, and major global markets. She is currently pursuing the Regulatory Affairs Certificate (RAC). Prior to joining Cerenovus, Marie held a position as a Quality Engineer in Boston Scientific Galway, working with Drug-eluting stents.*

## May 28<sup>th</sup>

\* Tuesday 28<sup>th</sup> from 8-11:15 a few people (6 or so) in WP3 that need to work on a specific model in the lab will have a session at Cerenovus. This session will be to decide on a protocol for their part of the WP.

Time		Presenter
9:00	<b>WP1/Management- updates</b>	<b>Laurian/Henk</b>
9:30	<i>Inter WP meetings</i>	
10:30	<i>Coffee break</i>	
11:00	<i>WP meetings for data description, WPs will sit together to discuss data they need/data they generate</i>	
11:30-12:00	<b>GA meeting-</b> one delegate per partner <i>See attached agenda</i>	<b>(ALL)</b>
12:00-12:30	Update on clot imaging developments	<b>Merel Boers/Praneeta</b>
12:30-13:30	<i>Lunch</i>	
13:30-14:30	workshop on software development QA **	<b>Piotr</b>
14:30-15:30	workshop on statistical digital twinning**	<b>Matteo/Gabor/Sven</b>
15:30-xxx	Room to discuss for all	

\*\* People not working on these subjects are free to find a place and discuss other matters, room 2002, also on the 2<sup>nd</sup> floor) can be used for break-out sessions.