Mediteq Forum Innovation
– Data driven research for health care

Are you involved and engaged in data driven research and development in the health care sector? Or maybe a future medical device or software where AI or ML may be included.

You and your colleagues are welcome to this introductory presentation covering several important areas for your research project but also many tips and trix of how to make your potential future product, data model or algorithm extra valuable and easy to bring into use.

This event is a free presentation from Mediteq Forum in cooperation with Cubist IT AB and Chalmers Innovationskontor. Mediteq Forum is a knowledge network for medical device organizations, located in Gothenburg since 2003.

When: Thursday 12 June 2025 at 13 to 16

Where: Chalmers Tekniska Högskola, Hörsal SB-H5, Göteborg

Sign up: Click

Some of the topics covered during the presentation are;

- ✓ Stakeholders – Who are you?
- ✓ Data access and data management of your data sets
- ✓ Ethical approval for data access – Svenska kvalitetsregister!
- ✓ Precision of your ML/AI/data-model – Sensitivity & Specificity is key!
- ✓ Who will use your data model?
- ✓ IP & lärarundantaget – Who owns the IP in your research project?
- ✓ Software – How to make reality of your data model
- ✓ How can your data model be delivered – Integrated or stand alone?
- ✓ Clinical data and evidence to be summarized in CEP and CER
- ✓ Processes & documentation – Make Plan, Do, Check, Act traceable!

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Since 2003 is the knowledge network Mediteq Forum available for you who want to be up to date with requirements, regulations and standards for medical devices. The events are often held in Swedish starting with the regulatory aspects and extends to interpretations, presentations, detailed discussions and practical examples including participants questions.

Mediteq Svenkebo AB
Kämpegatan 6
411 04 Göteborg

031-774 25 00
contact@mediteq.se
www.mediteq.se

Time schedule

13.00	Welcome and introduction
13.15	Data – the new goldmine. How to collect and maintain medical data, apply a clinical data model and achieve interoperability, enabling efficient data processing and serving as a basis for ML/AI and clinical decision support. Presented by Oliver Trepte at Cubist IT AB.
14.15	Coffe break
14.45	Regulations and stakeholders in Academy, Industry & Health care - Your role, responsibilities and ownership of results. Presented by Helen Sandelin at Mediteq.
15.45	Summary
16.00	End

There will be time for questions from participants, but please add your questions via the sign-up form, to get them covered during the presentation.

Warm welcome to sign up!
Helen Sandelin, Facilitator in Mediteq Forum

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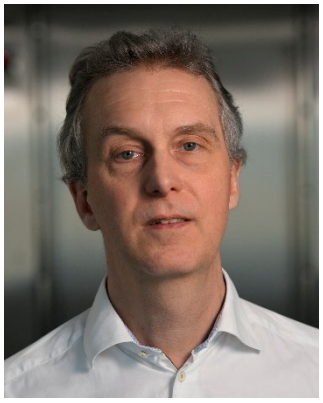
Presentation of speakers



Oliver Trepte, (Ph.D), CEO Cubist IT AB

Oliver has over 30 years of professional experience from research and development in the health sector.

Oliver has worked with a variety of medical devices, mostly in the field of data driven healthcare, including clinical decisions support and machine learning systems. With his long experience, he has supported a large number of projects regarding product strategy, architecture, design, implementation, regulatory strategy, management, and ways of working.

IT, SaMD, agile development, clinical data models, and data privacy are examples of current areas of special interest.

Helen Sandelin (BSc), CEO and Senior Consultant at Mediteq

Helen is a medical device regulatory consultant since 2007 with broad experience of regulatory compliance and standards of all type of devices including software and IVD's.

She has been involved in standardisation of software and medical electrical equipment since 2003 and is a member of the SNAIG advisory group for standardisation of AI and ML-enabled medical devices since 2020. She has also contributed to several research projects with industry, academia and health care organizations, e.g the Vinnova projects ASAP PoC and PreSIS.

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