



## Henrik Rindel Gudbergesen

MD, PhD, MPA, UCPH and CBS

Clinical trials  
Clinical Compliance  
Medical Device and Pharma

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PARTNER

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## Competences

- Project Management
- Clinical compliance (MDD)
- Clinical compliance (MDR/IVDR)
- Clinical trials and GCP
- Clinical Evaluations
- Expert insight within the healthcare sector
- Business innovation on the basis of science and research
- Fundraising
- R&D development and launch within Pharma, MedTech and Biotech
- ISO 13485 and 14155
- FDA 812 IDE

## Key results

- Management of international projects and direct
- Liaison with auditors and authorities in relation to R&D development and audits
- International speaking for 30-750 people incl. keynotes
- Clinical Trial execution for private companies, research institutions and start-ups
- +40 peer-reviewed publications
- Development and launch of solutions and products within the healthcare space
- Attraction of +6 million euro in soft funding
- Clinical experience, 15 years +
- Creation and review of IMDDs, clinical documentation packages, PERs, CERs and PMCF plans and reports for MD, IVD and SaMD
- Development of execution plans and strategic approach for PMCF/PMPF, CER/PER and risk evaluations

## Personal Characteristics

Henrik is an innovative, thoughtful, constructive and straight forward person that believes in open dialogue and enjoys cross-functional collaboration.

Henrik has vast experience across the healthcare sector within the clinical area – ranging from medical affairs to clinical compliance with pharmaceutical, MD and IVD products.

Henrik spends his free time with DIY projects, family, friends, and various adventurous sports.

## References

### Medicologic A/S (various clients)

Senior Consultant, Clinical Compliance

### Hedia ApS

Board Member

### Radiometer Medical ApS

Director, Medical Affairs & Clinical Compliance

Heading up Medical Affairs & Clinical Compliance in order to develop, execute and engage internal and external stakeholders in research and development, thought leadership, digitalization, research partnerships as well as medical/scientific/clinical communication

### IBM Nordic A/S

Chief Medical Officer

Medical lead within the development and application of innovative technology and methodology within the public healthcare sector, the life science industry, and the biotech sector across the Nordic countries. Specific focus areas are thought leadership as well as application of technological, medical and scientific advances in the digital transformation of the healthcare sector.

### Atonomics A/S, Hedia ApS and Embla ApS

Chief Medical Officer

Heading Medical Affairs and Clinical Development

### Novo Nordisk A/S

Pharmaceutical Medicine Physician

A headquarters-based talent development programme focusing on professional development while working with global responsibility for the project management of scientific communication, protocol development, advisory board activities, clinical trials execution, translational medicine themes, patient safety, and analyses of clinical, and pre-clinical data.

### Capital Region of Denmark

Principal Investigator and Senior Researcher

Coordinator for a Horizon 2020 programme funded eHealth project aiming to develop a web-based ICT platform for home-based monitoring of self-reliant patients, and leader for a EUROSTARS project aiming to develop a therapeutic drug monitoring solution for home use. The work included design processes, research, and clinical development.