

Curriculum Vitae

Personal information **Stine Hasling Mogensen**

Work experience

1. Employer: Danish Medicines Agency
 - Start date: 012021
 - End date: Ongoing
 - Position: Scientific Senior Advisor in the Data analytics Centre
 - Activities: Planning, design and prioritization of data analyses, member of board of directors at ISPE, Academia and government liaison, regulatory science engagement.
 - Country: Denmark
2. Employer: Danish Medicines Agency
 - Start date: 012020
 - End date: 122020
 - Position: Scientific Special Advisor in the Data analytics Centre
 - Activities: Planning and design of data analyses, Academia and government liaison, regulatory science engagement, PhD co_supervisor, mentor for industrial post doc
 - Country: Denmark
3. Employer: Danish Medicines Agency
 - Start date: 052019
 - End date: 122019
 - Position: Scientific Project Manager in the Data analytics Centre
 - Activities: Planning and design of data analyses, Academia and government liaison, regulatory science engagement
 - Country: Denmark
4. Employer: Danish Medicines Agency
 - Start date: 052017
 - End date: 052019
 - Position: EMA_Coordinator
 - Activities: Regulatory processes within the market authorisation application
 - Country: Denmark
5. Employer: Clinical Research Centre, Copenhagen University Hospital, Hvidovre
 - Start date: 032010
 - End date: 022017
 - Position: PhD student, Clinical Trial Manager, Medical writer
 - Activities: Responsible for all aspects of planning and conduction clinical phase 2 trials for the bupivacaine lozenge Co_operation with pharmaceutical companies, hospital pharmacy, hospital departments and investigators Supervision of MSc. pharm master students Patents application and Scientific publications Management of project nurses and study personnel
 - Country: Denmark

Education and training

1. Subject: Copenhagen University
 - Start date: 072011
 - End date: 102017
 - Qualification: PhD
 - Organisation: Identification of a clinical need for a new treatment options Reformulation and development of a well_known drug, Product information Design of clinical trial, Close corporation with hospital investigators, the GCP unit and the DKMA in introducing a new formulation of a well_known drug Safety assessments Project management Planning, risk assessments, initiation, conducting and evaluation of projects Management of multiple clinical studies, including a multicentre randomized controlled trial Trial documents and regulatory affairs Study protocol Writing and submission of applications to the Danish Medicine Agency, ethics committee, the Danish data protection agency and Danish hospital trial boards Vendor contract negotiations SOP development Case report files (CRF), e_CRF, patient diaries Trial master files Study medication Close co_operation with the hospital pharmacy regarding manufacturing Registration of trial medication in Danish hospital systems Evaluation of QC documents Packaging and labelling Administration of study medication Clinical trials Investigator_ and GCP meetings Good clinical practice Recruitment and inclusion of healthy subjects and patients in hospitals and private medical clinics Pain assessments Pain management Oncology treatments Audit from the DKMA Data management Data assessments and analysis Statistical analysis plan and report Clinical study plan and report Staff management, mentoring and teaching Management of project nurses, pharmacy staff, study personal and MSc. Master students External examiner, Pharma School, Copenhagen University Co_supervisor of MSc.Pharm Master thesis projects Copenhagen University External teacher on Clinical trial and GCP course at Copenhagen University
 - Country: Denmark
2. Subject: Copenhagen University
 - Start date: 092003
 - End date: 022010
 - Qualification: MSc. Pharm
 - Organisation: The MSc in Pharmaceutical Sciences from Copenhagen University focuses on the various phases of the drug development process, as well as learnings about pharmaceuticals from the discovery and development of new active substances to their effect and use in patients.
 - Country: Denmark

Additional information

Publications

Concept paper for EC on Real World Evidence (RWE) including registries (2022) Drafting group members: Peter Arlett, Anna Herks Vitezova, Maura O'Donovan, Ulla Wändel Liminga, Gabriel Westman, Kieran Breen, Martina Schüssler_Lenz, Markus Kalliola, Ewa Balkowiec_Iskra, Fabrice Eroukhmanoff, Miguel Angel Macia Martinez, Christian Gartner, Ioana Agache, Pasquale Marchione, Marilena Vrana, Alar Irs, Carla Torre, Julian Isla Gomez, Sylvie Benchetrit, Sabine Straus, Gunilla Andrew_Nielsen, Peter Mol, Alessandro Aiuti, Marjon Pasmooij, Jorg Zinserling, Stine Hasling Mogensen, Armando Magrelli, Alex Barbosa Correia, Caroline Pothet, Valerie Strassman, Xavier Kurz, Sandra Vanlievendael, Orsolya Eotvos, Jakob Wested. Annex I: Danish experiences regarding legal challenges in use of RWE, Authors: Stine Hasling Mogensen, Jakob Wested and Jesper Kjaer Scientific publications Andersson NW, Thieson EM, Laursen MV, Mogensen SH, Kjær J, Hviid A. Safety of heterologous primary and booster schedules with ChAdOx1_S and BNT162b2 or mRNA_1273 vaccines: nationwide cohort study, *BMJ* 2022;378: e070483, <http://dx.doi.org/10.1136/bmj-2022-070483> Bliddal M, Kildegaard H, Rasmussen L, Ernst M, Jennum PJ, Mogensen SH, Pottegård, Wesselhoeft R. Melatonin use among children, adolescents, and young adults. *A Danish Nationwide drug utilization study* Accepted for publication, June 2022: *European Child & Adolescent Psychiatry* Lund L.C., Hallas J., Nielsen H., Koch A., Mogensen S.H., Brun N.C., Christiansen C.F., Thomsen R.W., Pottegård A. Post-acute effects of SARS-CoV-2 infection in individuals not requiring hospital admission: a Danish population-based cohort study. *Lancet Infect Dis* 21(10), 1373-1382 (2021). [doi.org/10.1016/S1473-3099\(21\)00211-5](https://doi.org/10.1016/S1473-3099(21)00211-5) Jimenez-Solem E., Petersen T.S., Hansen, C. et al. Developing and validating COVID-19 adverse outcome risk prediction models from a bi-national European cohort of 5594 patients. *Sci Rep* 11, 3246 (2021). doi.org/10.1038/s41598-021-81844-x Sørensen AMS, Rasmussen L, Ernst MT, Mogensen S, Laursen MV, Jimenez-Solem E and Pottegård A (2020) Use of tramadol and other analgesics following media attention and risk minimization actions from regulators: a Danish nationwide drug utilization study. *Eur J Clin Pharmacol.* doi.org/10.1007/s00228-020-03016-6 Trelldal C, Petersen J, Mogensen S, Therkildsen C, Jacobsen J, Andersen O and Lyng Pedersen AM (2020), Characterization of burning mouth syndrome profiles based on response to a local anaesthetic lozenge. *Oral diseases.* 26(3):656-669. doi.org/10.1111/odi.13267 Mogensen S, Trelldal C, Kristensen CA, Bentzen J, Lawson-Smith L, Petersen J and Andersen O (2017), Effect of bupivacaine lozenges on oral mucositis pain: a randomized controlled multicenter phase II study. *PAIN Reports.* 2(5):e629. Mogensen S, Sveinsdóttir E, Sveinsdóttir K, Trelldal C, Jensen K, Jensen AB, Kristensen CA, Jacobsen J, Kreilgaard M, Petersen J and Andersen O (2017), Absorption of Bupivacaine after Administration of a Lozenge as Topical Treatment for Pain from Oral Mucositis. *Basic Clin Pharmacol Toxicol*, 120: 71–78. [doi:10.1111/bcpt.12644](https://doi.org/10.1111/bcpt.12644) Mogensen S, Sveinsdóttir K, Trelldal C, Jensen K, Nygård A, Mohammad A, Jensen FK, Kristensen CA, Petersen J and Andersen O (2016) No risk of aspiration after administration of new bupivacaine lozenge to healthy subjects and head and neck cancer patients with oral mucositis – a pilot study. *Journal of International Research in Medical and Pharmaceutical Sciences.* 10(2): 78-82. Mogensen S, Trelldal C, Sveinsdóttir K, Jensen K, Kristensen CA, Mogensen TS, Petersen J and Andersen O (2016) A novel lozenge containing bupivacaine as topical alleviation of oral mucositis pain in patients with head and neck cancer: a pilot study. *PAIN Reports.* 1(3):e571. Trelldal C, Jacobsen CB, Mogensen S, Rasmussen M, Jacobsen J, Petersen J, Pedersen AML and Andersen O (2016) Effect of a local anesthetic lozenge in relief of symptoms in burning mouth syndrome. *Oral Diseases* 22, 123–131 Trelldal C, Salale N, Mogensen S, Wettergren A, Rasmussen M, Petersen J, Andersen O, Jacobsen J (2014) New bupivacaine lozenge as topical anesthesia compared to lidocaine pharyngeal spray before upper gastrointestinal endoscopy in unsedated patients. *Clin Med InsightsGastroenterol.* 7:55–9 Mogensen S (2013) Smertebehandling af oral mucositis hos cancerpatienter. *BestPracticeOnkologis.* 14_15. (invited article) Mogensen S, Trelldal C, Feldager E, Pulis S, Jacobsen J, Andersen O, Rasmussen M (2012) New lidocaine lozenge as topical anesthesia compared to lidocaine viscous oral solution before upper gastrointestinal endoscopy. *Local and Regional Anesthesia* 5; 17_22 Mogensen S, Pulis S, Kristensen BB, Ravn L, Trelldal C, Rasmussen M, Mogensen T, Andersen O (2012) A new method to facilitate oro-tracheal intubation of awake patients: a pilot study. *Eur J Anaesthesiol.* 29(11):546–7

Projects

Bupivacaine lozenge for alleviation of oral mucositis pain _ Clinical studies on safety and efficacy in head and neck cancer patients Issued patent on a new formulation of bupivacaine, International Publication No.WO2012/146763A1. Moberg Pharma has bought the IP rights and is in process of conducting Phase III trials.

Memberships

Other Relevant Information