

Curriculum Vitae

Personal information **Katelijne De Swert**

Work experience

FEB 2024 – present: Clinical Assessor FAMHP

Responsibilities

- Evaluation of scientific information to determine the quality, safety and/or efficacy of medicinal products by analysing clinical results, referring scientific and regulatory guidance's, creating evaluation reports and define a risk/benefit profile and present these conclusions
- Provide scientific advice
- Keep up-to-date with relevant guidances, scientific evolutions and scientific literature
- Ensure practical and scientific harmonisation within the assessor's teams
- Participation in national and international working groups, scientific conferences and seminars

MAY 2021 – JAN 2024: Head – Data Management at MeiraGTx

Responsibilities

- Develops, implements and oversees operational data management activities performed by the DM team, ensuring quality and timely execution in accordance with project plans and according to GCP and other applicable regulatory guidelines
- Develops and organizes the DM team, ensuring resource allocations in line with corporate strategy as functional manager
- Ensures the data management review of all clinical study protocols, CSRs, publications, case report forms and supporting documentation with a focus on consistency and clarity
- Oversees CRO selection and contract/budget negotiations together with the study team and the Vendor Management representative
- Drives the strategy to ensure compliance to valid systems, which are maintained and monitored in line with corporate needs
- Supports the identification, review, evaluation and implementation of new technologies related to clinical data standards. Lead or participate in data standards process improvement initiatives
- If applicable, participates in scientific advice meetings and meetings with regulatory authorities (e.g. EMA and FDA)
- Participates in Regulatory Agency inspections and internal audits, as appropriate

- Ensures development of and maintains oversight over procedural and ancillary documents for collecting and cleaning of clinical data and standardization of data management procedures

SEP 2018 – MAY 2021: Head – Data Management at Argenx

2016 – 2018: Head – Data Management at Ablynx

2010 – 2016: Section Head Data Management at Ablynx

2004 – 2010: Clinical Data Manager at Johnson&Johnson

Education and training

2007: PhD in Medical Sciences - with great distinction

Ghent University
Fac. Medical Sciences, De Pintelaan 185,
9000 Ghent, Belgium

1996: Master of Biochemistry - with great distinction

Ghent University
Fac. Sciences, K.L. Ledeganckstraat 35,
9000 Ghent, Belgium

1994: Bachelor of Chemistry - with distinction

Additional information

Publications *Full papers*

Joos, G. F., K. O. De Swert, and R. A. Pauwels. 2001. Airway inflammation and tachykinins: prospects for the development of tachykinin receptor antagonists. *Eur.J.Pharmacol.* 429: 239-250.

Joos, G. F., K. O. De Swert, V. Schelfhout, and R. A. Pauwels. 2003. The role of neural inflammation in asthma and chronic obstructive pulmonary disease. *Ann.N.Y.Acad.Sci.* 992: 218-230.

Tournoy, K. G., K. O. De Swert, P. Leclere, R. A. Lefebvre, R. A. Pauwels, and G. F. Joos. 2003. Modulatory role of tachykinin NK₁ receptor in cholinergic contraction of mouse trachea. *Eur Respir J.* 21: 3-10

De Swert, K. O., K. G. Tournoy, G. F. Joos, and R. A. Pauwels. 2004. The role of the tachykinin NK₁ receptor in airway changes in a mouse model of allergic asthma. *J Allergy Clin Immunol* 113: 1093-9

De Swert, K.O. and G. F. Joos. 2006. Extending the understanding of

neuropeptides. Eur.J.Pharmacol. 533: 171-181

Joos, G.F. and De Swert, K.O. Tachykinins in: Encyclopedia of Respiratory Medicine Elsevier Ed. Laurent, G.J. and Shapiro, S.D. © 2006 Elsevier Ltd. (ISBN (set): 0-12-438360-2), volume 2, p 509-5017

Role of the tachykinin NK₁ receptor in a murine model of cigarette smoke-induced pulmonary inflammation. K. De Swert, K. Bracke, T. Demoor, G. Brusselle, G. Joos. *Respiratory Research* 2009; jan 01;10:37; (PMID: 19445658)

Book Chapters

De Swert, K. O., R. A. Lefebvre, R. A. Pauwels, and G. F. Joos. 2006. Role of the tachykinin NK₁ receptor in mediating contraction to 5-hydroxytryptamine and antigen in the mouse trachea. *Pulm Pharmacol Ther.* 2007; 20(5):588-95. Doi: 10.1016/j.pupt.2006.06.005. Epub 2006 Jul 11. (PMID: 16919985)

Abstracts

The absence of the tachykinin NK₁ receptor enhances baseline carbachol airway responsiveness but does not modulate allergen induced airway inflammation. De Swert et al. *Am.J.Respir.Crit.Care Med.*, 163, Abstract issue

The in vitro tracheal ring contractility is decreased in tachykinin NK₁ receptor knockout mice. De Swert et al. *Am.J.Respir.Crit.Care Med.*, 163, Abstract issue

Role of cholinergic and sensory nerves in ovalbumin-induced contraction of mouse trachea. De Swert et al. *Am.J.Respir.Crit.Care Med.*, 165, Abstract issue

The tachykinin NK₁ receptor augments goblet cell hyperplasia in a mouse model of asthma. De Swert et al. *Am.J.Respir.Crit.Care Med.*, 167, Abstract issue

Role of the tachykinin NK₁ receptor in cigarette smoke-induced airway inflammation in mice. De Swert et al. *Am.J.Respir.Crit.Care Med.*, 167, Abstract issue

Influence of the tachykinin NK₁ receptor on long term smoke-induced pulmonary changes in mice. De Swert et al. *Am.J.Respir.Crit.Care Med.*, 169, Abstract issue

Projects

Memberships

Other Relevant Information

- Extensive experience with Biologics License applications at FDA ensuring compliance with data standards requirements (CDISC-SDTM)