# Information session on the Biobank legislation in Belgium

**19 JUN 2018**  
**Brussels**

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By Nick Van Gelder
On the November 1st, 2018, the Royal Order on Biobanks (March 8th 2018) will enter into force. Biobanks will need to inform the FAMHP about their activities, the identity of the “manager”, etc. and they will be expected to comply with a new set of legal obligations. During this session, a brief overview of the legal framework and its practical implications will be discussed.

By Gwendolyn Goedbloed
Responsible for the Janssen R&D global Biobank ensuring compliance when working with any type of human samples in research supporting all therapeutic area’s and center of excellence’s across the entire Janssen community. This responsibility also includes compliance on clinical regulations and local legislations.

By René Custers
The new Biobanking legislation has consequences for everybody involved in collecting and using human bodily materials for use in scientific research. In this presentation this legislation will be approached from a public research perspective. How will the legislation affect the end users? What are the consequences for the exchange of materials? And how about import and export?

By Kathleen Devos
Ablynx will request to be registered as Belgian Biobank in order to collect, store and use human body materials for their internal scientific research in compliance with the new Biobank legislation: how are we preparing?

By Laurent Dollé
The Royal Decree on Biobanks is now published and has important consequences for the organization, functioning and activities of biobanks. In addition to the rules it imposes, it also brings into force the amendments made in 2013, 2014 and 2016 to the law of 19 December 2008 on the human biospecimen samples. New rules are then applicable, particularly with regard to the conditions for sampling the sample and its traceability (or not), the opinions to be solicited from the ethics committees, the notification of the biobanks, the reports to be sent to the FAMHP, the operating conditions of the biobanks ... The presentation will illustrate the actions that BWB is putting in place to help and support its partners and end-users with regard to this new legislation in their daily life.

Topic descriptions:

Biobanks in Belgium

R&D in Pharma

R&D in VIB

R&D in life sciences SME’s

R&D in public Biobanks
President BBMRI.be

Prof. Sofie Bekaert was trained as a doctor in Applied Biological Engineering. After 10 y of research, setting up a research platform on biological aging, next generation sequencing and biomarkers, she became valorization and innovation manager. Currently she is the head of the Clinical Research Center (http://www.bimetra.be) at Ghent University Hospital in collaboration with Ghent University.

As the head of Bimetra, she has the responsibility over ~25 coworkers in the daily management of the central point of contact for facilitation of different aspects of translational biomedical research (ethico-legal aspects, datamanagement and monitoring of clinical trials, research and innovation management within the hospital, biobanking, big data). The Bimetra Biobank is a novel high quality controlled biobank facility, operational since 2015 and bringing together several biobank collections (~70,000 annotated samples) and initiatives (Belgian Virtual Tumourbank, Flemish Biobank Network and local strategic collections).

Prof. Bekaert is liaising to strategic translational initiatives concerning biobanking and clinical research and innovation, both at the regional and (inter)national level and in close collaboration with governmental bodies. In 2017, Sofie Bekaert was appointed president of the Board of directors of the BBMRI.be, in addition she is elected councilor within the European, Middle-eastern and African Society for Biopositories and Biobanking (www.esbb.org) and is member of the executive committee of Eupati.be (http://eupati.be/).

Prof. Bekaert is involved in multiple research and societal valorization projects concerning stakeholder involvement and participation in research (e.g. King Baudouin Foundation – multistakeholder dialogue for prioritization of research).

As of 1st June 2018 Sofie bekaert will be managing the reverse translation program of the Grand Challenges initiative within the Flemish Institute for Biotechnology (www.vib.be).

Regulatory & responsible research manager at VIB

René Custers is trained in molecular biology and joined VIB – a life sciences research institute based in Flanders – in 1997. He has more than 20 years of experience in regulatory affairs, biosafety, and societal aspects of modern biotechnology. He is an expert in the legislation and safety of GMOs and genome edited organisms. At VIB he coordinates the institutes’ policies on regulatory compliance, (bio) safety, ethics and integrity. He is also involved in science communication activities to a wider audience. He is a member of the Belgian Biosafety Advisory Council, and secretary of the European Biosafety Association.
Kathleen Devos

Section Head Technical Expert team “Discovery-Lead Characterization-Cell Based Solutions” at Ablynx

1982: Master in Biology (Physiology-Biochemistry)
1986: PhD in Science (UGent Lab. Molecular Biology, Prof. Fiers)
1986-1989: post doc (UGent Lab. Molecular Biology, Prof. Fiers)
1990-2011: Innogenetics in several functions: Research Scientist, Line Manager different units (Molecular Biology/Protein expression; R&D general services team), Project Leader Product & Platform Lifecycle Projects
2012-2018: Ablynx as Section Head Technical Expert team “Discovery-Lead Characterization-Cell Based Solutions”

Laurent Dollé

Managing Director at Biothèque Wallonie Bruxelles

Laurent Dollé is a scientist in Biomedical Sciences with 16 years of experience in Cell Biology and Molecular Biology with interests on healthcare systems and innovative technologies/-devises. Laurent has a deep knowledge in the field of breast cancer research (growth, migration, invasion and metastasis), in hepatology (fibrosis, cirrhosis, and hepatocarcinoma), and liver regeneration (stem cells, liver repair and therapies, mouse models).

In 2012, Laurent became Assistant Professor at the Free University of Brussels VUB, and from 2016, he became the operating manager of the biobanks network from Wallonia-Brussels regions (BWB) allowing him to accumulate a profound awareness on the vast ecosystem of Biobanking (collection, harvesting, storage, distribution compliant with international quality standards (GLP/GMP and ISO standards) and regulations (law and royal decree). Since September 2017, Laurent is the managing director at BWB.

Sandrine Fontaine

Head Medical Governance for Human Subject Research at GSK Biologicals S.A.

Bioengineer by training, I am working in the Pharmaceutical industry since more than 15 years. Over my carrier I had various role in GCP/GLP auditing, ISO implementation, clinical operations and Risk management. I am currently working for GSK Biologicals S.A. in the Medical Governance and Bioethics group. I am supporting the deployment of the Biobank legislation. I am part of the Compendium deployment among other stakeholders of the industries, academic, regulator and Ethical Committee.
Director at Janssen, Pharmaceutical Companies of Johnson and Johnson

Gwendolyn graduated as Industrial Engineer in Chemistry and Automation and joined Tibotec in 1999 setting up the Compound Logistics department. Few years later she became operational head of the Virco Diagnostics Lab.

In 2011 Gwendolyn led the implementation of the Biobank in Beerse, the first Biobank in Janssen. She built the department and designed a process to ensure compliance to local Belgian Biobank legislation. More recently, Gwendolyn took additional managerial responsibilities for the Spring House Biobank team in US.

In 2013, Gwendolyn took the global lead to initiate the Janssen Global Biobank Community of Practice. Under her leadership, the team implemented 1 global process and 1 global centralized database covering all Janssen Biobank sites: Spring House, La Jolla, Raritan, Beerse, Leiden and Shanghai.

In 2017, Gwendolyn took an additional global responsibility on Quality & Compliance and Environment, Health and Safety activities. Supporting the scientific community by building connectivity with business partners to create a culture of safe and compliant practices.

Managing Director at Silver Arrow

After a PhD in genetics in the renowned AgBiotech Research Department of Prof. Van Montagu and Schell (University Ghent), Dr. Joos started his professional career in Plant Genetic Systems. In PGS, Henk was instrumental in setting up a succesfull Hybrid Canola Business in Canada and in the sale of PGS to AgrEvo. Henk had subsequently international positions with AgrEvo, Aventis Crop Science and Bayer CropScience.

After a career switch towards the development of new energy crops, Henk continued his international activities in D1 Oils and Quinvita. In 2013 Henk became managing director of FlandersBio, one of the leading life sciences clusters in Europe. Under his leadership FlandersBio grew to 350 members, financial self sufficiency and a cluster with international fame. Henk started in 2018 Silver Arrow, a project management firm with focus on international business and financial growth of promising life sciences companies in Belgium and Europe. Henk also became recently the Director Life Sciences, Biotech and Agriculture for AGIO Capital and Business Solutions with a focus on China deployment.
Conseiller - Adviseur at Minister van Sociale Zaken en Volkgezondheid / Ministre des Affaires sociales et de la Santé publique, Maggie De Block

Diane Kleinermans works as advisor to the Minister of Public Health and Social Affairs since 2015. Her main responsibilities include clinical trials, human body material but also the BeNeLuxA initiative.

Diane has a medical background and a broad experience in various fields. She started her career as GP in Brussels but rapidly collaborated with the pharmaceutical industry.

Her first employer was Pfizer where she stayed for more than 15 years, working in early development and creating their Phase I Unit at the Erasme hospital (Brussels). She managed the unit for 10 years, then left Belgium and worked as medical director of CRO’s in France and the UK, before joining Novartis Ophthalmics as head of the scientists group in Zurich.

She then came back to Belgium where, after a short experience in the regulatory department of GSK Biologicals, she joined the NIHDI as internal expert to the Commission of Drugs reimbursement, being amongst others in charge of orphan drugs assessments.

Jurist at FAMHP

Nick is one of the FAMHP’s legal advisors. His field of expertise pertains to the legislation regarding the use of human material, both for therapeutic and scientific purposes. In 2013, he presented his PhD research, entitled “Naar een commercialisering van menselijk lichaamsmateriaal?” (Towards a commercialisation of human bodily material), and he has been active at the University of Antwerp as a visiting professor at the Antwerp Health Law and Ethics Center (AHLEC).
Managing Director at ECCRT

Prof. Dr. Benedikt Van Nieuwenhove obtained his degree in Pharmaceutical sciences from the University of Gent, Belgium in 1991. Between 1991 and 1997 he worked as a quality assurance manager at a laboratory for medical biochemistry & clinical analysis in Gent. In 1997 he finished his Ph.D. in Pharmaceutical Sciences at the University of Gent in Belgium. Since then till 2014 he had been working for Harrison Clinical Research. He started his career as clinical operations manager and general manager of the Benelux operations. In 2000, he founded their own training Academy, the “European Centre for Clinical Research Training” (ECCRT) and in 2007 he became a member of the Board.

From 2008-2011 he acted as the Vice President Global Operations of the Harrison Clinical Research group. In January 2011, he was elected Chief Executive Officer of Harrison Clinical Research. In that position he was involved in the merge with Synteract to form SynteractHCR. He has been instrumental in integrating the two organisations during 2013 and 2014.

Since its creation in 2000, Benedikt has been the Managing Director of ECCRT. Having been in the field of Clinical Research for about three decades he has amassed a wealth of knowledge and skills within this field. Over the years he has supported the Pharma Industry as well as other players in the healthcare sector by providing them with the skill sets to deal with the challenges in their job and to make them efficient players in study success.

Since 2016 he is lecturing “Management of Clinical Research” at the Faculty of Pharmaceutical Sciences, University Ghent.

Practical information:

Date: 19 JUN 2018 (14h30 - 18h00). Doors open at 14h00.
Location: BIP Brussels, Rue Royale 2, 1000 Brussels, Belgium.
Fee:
- For Academics: 70 € (excl. VAT)*
- For Industry: 150 € (Excl. VAT)

*Also for all students, hospital staff, public and non-profit organisations.