

Curriculum Vitae

Personal information Work experience

Christophe Lahorte

- 1. Employer: Gent University
 - Start date: 091998

 - State date: 082004
 End date: 082004
 Position: Scientific Personnel (Research & Development)
 Activities: Research activities in preparation of a PhD. thesis in Pharmaceutical Sciences at the Gent University, PhD. thesis title: "123! 99mTc_labelled Annexin V for in vivo detection of programmed cell death and 123I_MAb 14CS as potential SPECT_ligand for imaging tumous contents." (September 1998 - April 2004) This research work was conducted in collaboration with the several national and international research group these activities, experience was obtained in research and development, quality control, and (pre)clinical evaluation of radiopharmaceuticals analytical chemistry and biotechnological and molecular imaging techniques. • Collaborations with pharmaceutical industry: (Radio)chemical development, quality control, release testing and (pre)clinical evaluation of diagnostic radiopharmaceuticals in collaboration with Theseus In Corporation, a division of North American Scientific, Boston, USA (September 2002 _ August 2004) These tests were conducted at the Labor Radiopharmacy (ISO 17025 certified) of the Gent University which is officially recognized as national control laboratory by the Federal Gover Health in Belgium for the quality control and analysis of pharmaceuticals (BS 18.11.1988, MS 18.01.2001) • Set up and performance of pha trials in diagnostic oncology and cardiology, in collaboration with the Departments of Nuclear Medicine, Radiotherapy, Head and Neck Surger Pathology and Cardiology at the Gent University Hospital, Theseus Imaging Corporation, Boston, USA and Fisher Clinical Services, West Sus 2001 _ August 2004)
 - Country: Belgium
- 2. Employer: federal agency for medicines and healthcare products (FAMHP)

 Start date: 092004

 - End date: 032009 Position: chemical_pharmaceutical assessor
- Activities: Chemical_pharmaceutical assessor of national scientific & regulatory advice requests related to the development of new me for human/veterinary use Chemical_pharmaceutical assessor of European scientific advice requests related to the development of new rad products for human use; in concertation with the Scientific Advice Working party (SAWP) of the European Medicines Agency (EMA) Chemical_pharmaceutical assessor of clinical trial applications with investigational (i.e. non_licensed) and licensed medicinal products for hu including in vivo diagnostics) • Chemical_pharmaceutical assessor of paediatric investigation plans (PIP's) for drug products in concertation Committee (PDCO) of the European Medicines Agency (EMA) and the PDCO Formulation Working Group • Assisting chemical_pharmaceutica GMP inspections related to the manufacturing of radiopharmaceuticals; in collaboration with the Directorate_General Inspections of the Federal Inspection I Medicines and Health Products (FAMHP) • Provision of scientific and regulatory support in the development and peer_review of (inter)nation. pharmaceutical legislation regarding radiopharmaceuticals, clinical trials, etc. in collaboration with different national and European regulator bodies. • Development of Standard Operating Procedures (SOP's) for the assessment and provision of scientific and regulatory advice regard medicinal products, paediatric drug products, medicinal products produced by genetically modified organisms, etc.

 • Country: Belgium

 3. Employer: federal agency for medicines and healthcare products (FAMHP)
- - Start date: 042009 End date: 042017

 - Position: Head of the Unit for national scientific_regulatory advice & knowledge management

 Activities: Operational and strategic management of the Unit for national scientific & technical/regulatory advice & knowledge management FAMHP
- Country: Belgium
 4. Employer: federal agency for medicines and health products
 - Start date: 052017 End date:

 - Position: Head of the national Innovation Office & Scientific_Regulatory Advice Unit

 Position: Head of the national Innovation Office & Scientific_Regulatory Advice Unit
 Activities: _ Operational and strategic management of the national Innovation Office and Unit for national scientific & technical/regulator the FAMHP • Member of the "EU Innovation Offices Network (EU IN)", coordinated by the Heads of Medicines Agencies (HMA) and the Europa Agency (EMA), (March 2015 - present) • Member of the EU IN's "Borderline & Classification working group" (i.e. the former HMA's "Medicine borderline and combination products co_ordination working group" coordinated by the EU IN and the European Medicines Agency (EMA), (Nupresent) • Alternate Member of the MDCG "Borderline & Classification working group (BCWG)" coordinated by the Medical Device Coordination Group (March 2018 - present) • Member of the MDCG "New Emerging Technologies working group (NET)" coordinated Device Coordination Group (MDCG) of the European Commission, (February 2019 - present) • Member of the Internal Market Committee gr Intelligence & Digital Economy" coordinated by the Interministerial Economy Commission (IEC) of the Federal Public Service of Economy in ceg. the High Level Working Group on Competitiveness and Growth van HLG COMPGROW), Directorate A - Artificial Intelligence & Digital Indu
Directorate General for Communications Networks. Content and Technology of the European Commission (May 2018 - Present) Directorate_General for Communications Networks, Content and Technology of the European Commisssion (May 2018 - Present)

Country: Belgium

Education and training

- Subject: Faculty of Pharmaceutical Sciences (Gent University)
 Start date: 091995

 - End date: 061998 Qualification: Master in Pharmaceutical Sciences
 - Organisation:
- Country: Belgium 2. Subject: Faculty of Pharmaceutical Sciences (Gent University)

Start date: 091998

End date: 042004

Qualification: PhD in Pharmaceutical Sciences

Organisation: Country: Belgium

Additional information

Publications

PUBLICATIONS IN INTERNATIONAL PEER_REVIEWED JOURNALS 1. Lahorte C., Dumont F., Slegers G., Van De Wiele C., Dierckx R.A., and Philippé J., Synthesis stability of 123I_labelled annexin V: A potential agent for SPECT imaging of apoptotic cells, J. Labelled Comp. Radiopharm. 43 (7), 739_750, 2000. 2. De Sutter PUBLICATIONS IN INTERNATIONAL PEER_REVIEWED JOURNALS 1. Lahorte C., Dumont F., Slegers G., Van De Wiele C., Dierckx R.A., and Philippe J., Synthesis stability of 123I Labelled annex in V: A potential agent for SPECT imaging of apoptotic cells, J. Labelled Comp. Radiopharm. 43 (7), 739, 750, 2000. 2. De Sutter Taeymans Y., Dierckx R.A., and Slegers G., Cell death in myocardial infarction, Lancet 356 (9239), 1439_1440, 2000. 3. Lahorte C., Slegers G., Philippé J., Van Dierckx R.A., Synthesis and in vitro evaluation of 123I_labelled human recombinant annexin V, Biomol. Eng. 17 (2), 51_53, 2001. 4. Van de Wiele C., Lahorte C. Boerman O., Goethals I., Slegers G., and Dierckx R.A., Nuclear Medicine Imaging to predict response to radiotherapy: a review, Int. J. Radiat. Oncol. Biol. Phys 2003. 5. Lahorte C., Van de Wiele C., Bacher K., Van den Bossche B., Thierens H., Van Belle S., Slegers G., and Dierckx R.A., Biodistribution and dosimetry stur 123I_rh_Annexin V in mice and humans, Nucl. Med. Commun., 24, 871_880, 2003. 6. Van de Wiele C., Lahorte C., Vermeersch H., Loose D., Mervillie K., Stein Vanderheyden J.L., Cuvelier C.A., Slegers G., and Dierckx R.A., and Dierckx R.A., Quantitative tumour apoptosis imaging using 99mTc_HYNIC_Annexin single photon emission co tomography, J. Clin. Oncol., 21 (18), 3483_3487, 2003. 7. Vandenbulcke K., Devos F., Offner F., Philippé J., Apostolidis C., Molinet R., Nikula T.K., Bacher K., D., Lahorte C., Thierens H., Dierckx R.A., and Slegers G., In vitro evaluation of 213Bi_Rituximab versus external gamma irradiation for the treatment of B_CLL biological efficacy with respect to apoptosis induction and chromosomal damage, Eur. J. Nucl. Med. Mol. Imaging, 30 (10), 1357_1364, 2003. 8. Vermeersch H., Lahorte C., Mervillie K., Dierckx R.A., Steinmetz N.D., Vanderheyden J.L., Cuvelier C.A., Slegers G., and Van de Wiele C., 99mTc_HYNIC Annexin_Vimaging of neck carcinoma, a comparison with computerized tomography, Nucl. Med. Commun., 25 (3), 259_263, 2004. 9. Lahorte C., Bacher K., Burvenic article), Eur. J. Nucl. Med. Mol. Imaging, 31 (6), 887_919, 2004. 14. Cornelissen B., Lahorte C., Kersemans V., Capriotti G., Bonanno E., Signore A., Van De Wi R.A. and Slegers G., In vivo apoptosis detection with radioiodinated Annexin V in LoVo tumour bearing mice following Tipifarnib (Zarnestra, R115777) farnesyltr inhibitor therapy, Nucl. Med. Biol., 32 (3), 233_239, 2005. 15. Lancel S., Petillot P., Stebach N., Lahorte C., Danze P.M., Vallet B, Marchetti P., Neviere R, Apopi factors and myocardial dysfunction in endotoxemic rats, Crit. Care Med. 33(3), 492_496, 2005. 16. Petillot P., Lahorte C., Bonanno E., Signore A., Lancel S., Ne Marchetti Ph., Vallet B., Slegers G. and Nevière R., Annexin V detection of lipopolysaccharide_induced cardiac apoptosis, Shock, 27 (1), 69_74, 2007. 17. Rotte Vakaet L., Lahorte C., Vermeersch H., Van Belle S. and Van de Wiele C., 99mTc_HYNIC Annexin_V imaging of tumors and its relationship to response to radioth chemotherapy, Q. J. Nucl. Med. Mol. Imaging, 51 (2), 182_188, 2007. PUBLICATIONS IN SCIENTIFIC BOOKS 1. Arano. Y., Boersma H., Casacó, A., Castiglia, S. Signore A., Solanki K. and Wadhwa M., Clinical Translation of Radiolabelled Monoclonal Antibodies and Peptides, IAEA Human Health Series No. 8, International Agency (Vienna), ISBN 978_92_0_108809_3, ISSN 2075_3772, (http://www.iaea.org/books), 2009. PUBLISHED GUIDELINES 1. Janssens W., Lahorte C., and Guidance to the conduct of exploratory (phase 0) trials in Belgium, (https://www.famhp.be/sites/default/files/exploratory_guideline_clinical_trials_in_belgium_v3_07_06_2016_2.pdf), 2007 (version 1) & 2012 (version 2). 2. Wi Pauwels K., Goossens M., Baldo A., Delgado R., Lenaers A., Lahorte C., Overview of procedures for submitting an application for clinical trials with GMO_medicin human and veterinary use in Belgium, (http://www.fagg_afmps.be/en/human_use/medicines/scientific_technical_advice/regulation), 2015. HEALTH

ASSESSMENT (HTA) STUDIES 1. Contributing expert to the HTA Study 2016_01 "Responsible use of high_risk medical devices: the example of 3D printed medicoordinated by the Belgian Health Care Knowledge Centre (KCE), KCE report 297A,

coordinated by the Belgian Health Care Knowledge Centre (KCE), KCE report 297A, (https://www.kce.fgov.be/en/responsible_use_of_high_risk_medical_devices_the_example_of_3d_printed_medical_devices), January 16th 2018. INTERVIEWS interview regarding "The implementation of a national Innovation office at the Federal Agency for Medicines and Healthcare Products", Pharma.Be newsletter nr (http://pharma.be/nl/news/actualiteit/103_fagg_lahorte.html), May 19th 2017. 2. Video interview with Pharma.Be regarding patient involvement in clinical resestific advice procedures, presented at the Pharma.Be's Clinical Trials Forum 2019 (https://www.youtube.com/watch?v=Z_JYZNVRF7g&feature=youtu.be), May 19th 2017. Raising awareness about the usefulness and necessity of policy partnership. Master Thesis from Alicia Noyez, promotors Prof. Dr. Isabelle HUYS (KU Leuven) and Dr. Katrien De Groote (INNOSENS), March 22nd 2021. 4. Interview with the Embassy in Brussels regarding "Pharmaceutical Management systems in Belgium and the EU" in view of the implementation of a Canadian Drug Agency Transiti October 13th 2021. 5. Interview with Deloitte Consulting on behalf of Flanders Investment & Trade (FIT) regarding "advanced (immuno)therapies: identifying the propriet of the Elemish immunotherapy ecosystem by manning the existing canabilities and henchmarking these with selected foreign hotsports." Monitor Deloitte E gaps in the Flemish immunotherapy ecosystem by mapping the existing capabilities and benchmarking these with selected foreign hotspots", Monitor Deloitte, F 2022. 6. Interview with Erasmus University Rotterdam regarding "the accessibility of repurposed drug products" as part of the master thesis from Amy Bouman gaps in the Flemish immunotherapy ecosystem by mapping the existing capabilities and benchmarking these with selected foreign hotspots", Monitor Deloitte, F. 2022. 6. Interview with Erasmus University Rotterdam regarding "the accessibility of repurposed drug products" as part of the master thesis from Amy Bounna Interview with the Wallonia Export and Investment Agency (AWEX) regarding "Introduction to the regulatory system in Europe and the role of the Belgian Ager and Health Products", presented at the BioPlus_Interphex Korea 2022 life science event in Seoul (https://www.bioplusinterphex.co.kr/en_us/conference/Session SessionsDetail.2886.156729.business_session_embassy_of_belgium_introduction_to_the_regulatory_system_in_europe.html), in collaboration with the Belgain August 3rd 2022. PROCEEDINGS OF INTERNATIONAL PEER_REVIEWED CONFERENCES 1. Lahorte C., Dumont F., Slegers G., Van De Wiele C., De Sutter J., and Synthesis and in vitro evaluation of 123I_labelled human recombinant annexin V, 9th European Congress on Biotechnology (ECB 9), Juli 11_15, 1999, Brussels, Proceedings p. 78, 1999_2000, Ed. Hofman M., Branche Belge de la Société de Chimie Industrielle, ISBN 805215_1_5. (poster presentation) 2. Vandenbulcke K. Janssens A., Molinet R., Apostolidis C., Janssens W., Lahorte C., Brans B., Slegers G., Thierens H., Dierckx R.A., Philippé J., and Offner F., Alpha_radioimmunot chlorambucil sensitive and resistant B_CLL in vitro, B Cell lymphoproliferative disorders II, June 2_5, 2001, Amsterdam, The Netherlands, Contributions of Imm Molecular and Cell Biology to Understanding and Treatment, S66, p. 76, 2001, Eds. Chiorazzi N., Schulman P., Ferrarini M., Rai K.R., Imedex (poster presentative Vandenbulcke K., De Vos F., Janssens A., Philippé J., Thierens H., Slegers G., Noens L., Dierckx R.A., Lahorte C., and Offner F., Alpha_immunotherapy in B_CLL General Meeting of the Belgian Hematological Society (BHS), Februari 1_2, 2002, Brussels, Belgium, BHS Proceedings P32, p. 61_62, 2002. (poster presentatio Lahorte C., N Van De Wiele C., and Dierckx R.A., Synthesis, biodistribution and dosimetry studies of 123I_labelled annexin V in mice: A potential SPECT_ligand for visualisativ cells, 9th Symposium of the International Society of Radiolabeled blood elements (ISORBE), October 20_23, 1999, Rio De Janeiro, Brazil, Nucl. Med. Commun. 1999. (oral presentation) 2. Lahorte C., De Sutter J., Van De Wiele C., Foubert L., De Winter F., De Cupere C., Taeymans Y., Van Nooten G., Slegers G., and Diercks. Paris, France, Eur. J. Nucl. Med. 27 (8), p. 1055, PS 180, 2000. (poster presentation) 4. Pétillot P., Lahorte C., Nevière R., Marchetti Ph., and Slegers G., Expression of the European Society of Radiolabeled blood elements (ISORBE), October 20 De Janeiro, Brazili, Nucl. Med. Commun. 20 (10), p. 948, 1999. (poster presentation) 3. Brans B., Lahorte C., Jacobs F., Offner F., Slegers G., Thierens H., and use of alpha_emitting isotopes in a clinical environment: the requirements, 13th Annual congress of the European Association of Nuclear Medicine (EANM), Sept Paris, France, Eur. J. Nucl. Med. 27 (8), p. 1055, PS 180, 2000. (poster presentation) 4. Pétillot P., Lahorte C., Nevière R., Marchetti Ph., and Slegers G., Ex viv sepsis induced cardiomyocyte apoptosis with 123I_annexin V, 7th Congress of the European Society for Analytical Cellular Pathology (ESACP), April 1_5, 2001, Anal. Cel. Pathol. 1,2 (22), p. 35, H011, 2001. (oral presentation) 5. Lahorte C., Pétillot P., Nevière R., Marchetti Ph., and Slegers G., The myocardial uptake of is increased in septic rats, 14th International Symposium on Radiopharmaceutical Chemistry (ISRC), June 10_15, 2001, Interlaken, Switzerland, J. Labelled. Co. is increased in septic rats, 14th International Symposium on Radiopharmaceutical Chemistry (ISRC), June 10_15, 2001, Interlaken, Świtzerland, J. Labelled. Co (44), S430_S432, 2001. (poster presentation) 6. Philippé J., Vandenbulcke K., De Vos F., Janssens A., Molinet R., Apostolidis C., Janssens W., Nikula T., Lahort Slegers G., Thierens H., Dierckx R.A., and Offner F., The apoptogenic effect of alpha_particle emittor 213_Bi conjugated to B_Cell antibodies in vitro in B_CLL, 1 Euroconference on Clinical Cytometry: "from pathogenesis to therapy", September 21_25, 2001, Urbino, Italy, J. Biol. Regulators and Homeostatic Agents 15, p (poster presentation) 7. Pétillot P., Lahorte C., Nevière R., Slegers G., Vallet B., Formstecher P., and Marchetti Ph., Myocardial protection is provided by the cas zVAD.fmk during septic shock, 14th Annual Congress of the European Society of Intensive Care Medicine (ESICM), September 30_ October 3, 2001, Geneva, S Intensive Care Med. 27 (43), Suppl. 2, 5146, 2001. (oral presentation) 8. Offner F., De Vos F., Vandenbulcke K., Janssens A., Molinet R., Apostolidis C., Janssel Lahorte C., Brans B., Slegers G., Thierens H., Dierckx R.A., and Philippé J., Comparison of in vitro apoptosis induction by alpha_irradiation versus gamma_irrad 43rd Annual Meeting of the American Society of Hematology (ASH), December 9_11, 2001, Orlando, Florida, USA, Blood 98 (11), p. 4910, Part 2, 2001. (poster Philippé J., Vandenbulcke K., De Vos F., Janssens A., Molinet R., Apostolidis C., Janssens W., Nikula T., Lahorte C., Brans B., Slegers G., Thierens H., Dierckx R. Evaluation of anti_CD19/CD20 conjugated to the alpha_particle emittor 213_Bi in apoptosis induction in vitro in B_CLL, IXth International Workshop on CLL (IW 22_24, 2002, San Diego, California, USA, Leukemia and Lymphoma 42, (Suppl. 1), PS95, p. 55_56, 2001. (poster presentation) 10. Lahorte C., Pétillot P., Marc Bonanno E., Signore A., and Slegers G., Ex vivo detection of myocardial cell death with 1231_annexin V in a rat model of septic shock Association of Nuclear Medicine (EANM), August 31 _ September 4, 2002, Vienna, Austria, Eur. J. Nucl. Med. Mol. Imaging 29 (Suppl. 1), S91, OS164, 2002. (or 11. Lahorte C., Burvenich I., Bacher K., Thierens H., Coene E., Schelfhout V., Cuvelier C., and Slegers G., Synthesis, biodistribution and dosimetry of the 1231_mice: A potential SPECT_ligand for radioimmunodetection of tumour growth and metastasis in vivo, 15th Annual congress of the European Association of Nuclea (EANM), August 31 _ September 4, 2002, Vienna, Austria, Eur. J. Nucl. Med. Mol. Imaging 29 (Suppl. 1), 577, OS112, 2002. (oral presentation) 12. Pétillot P., Newière R., Marchetti P., Signere A., and Vallet B., Endotoxin_induced myocardial apoptosis and cyclosporin A, 15th Annual Congress of the European Society of Medicine (ESICM), September 29 _ October 2, 2002, Barcelona, Spain, Intensive Care Med. 28 (Suppl. 1), 594, nr. 356, 2002. (poster presentation) 13. Lahortd Marchetti Ph., Bonanno E., Signore A., and Slegers G., Therapeutic evaluation of caspase inhibitors with 1231 Annexin V in a rat model of endotoxin_induced m apoptosis, 16th Meeting of the International Research Group in Immunoscintigraphy and Immunotherapy (IRIST): "Peptide radiopharmaceuticals in diagnosis ar cancer and inflammation/infection", May 8. 10, 2003, Capri, Italy, Cancer Biotherapy & Radiopharmaceuticals 18 (2), p. 288_289, 2003. (poster presentation) 1 C., Lahorte C., Vermeersch H., Loose D., Mervillle K., Steinmetz N.D., Vanderheyden J.L., Cuvelier C.A., Slegers G., and Dierckx R.A., Quantitative tumour apop using 99mTC_HYNIC Annexin single photon emission computerized tomography, 16th Annual congress of the European Association of Nuclear Medicine (EANM), 2003, Amsterdam, The Netherlands, Eur. J. Nucl. Med. Mol. Imaging 30 (Suppl. 1), S159, no. 50145, 2003. (conster presentation) 15. Vermeersch H., Loose D., Lahor Dierckx R.A., Steinmetz N.D., Vanderheyden J.L., Euvelier C.A., Slegers G., and Vallet B., Marchetti P., Slegers G., and Vallet B., Marchetti P., and Nevi

Projects

PROJECT MANAGEMENT EXPERIENCE: • Development and implementation of the "alpha_emitters laboratory" within the Dept. of Nuclear Medicine, Gent Univers the start_up of alpha_radioimmunotherapy in Non_Hodgkin's Lymphoma as part of a European research project, (September 1998 _ October 2001) • VirRAD pr (Internet_based Virtual Radiopharmacy Learning Community), http://www.virrad.eu.org, EU_project no: 15T. 2001_32291, (March 2002 _ August 2004) • Part member of the National Competent Authorities consortium for the Horizon 2020 project "SC1_HCO_05_2018: Strengthening regulatory sciences and supporting scientific advice (STARS)", a Coordination and Support Action on Training Academia in Regulatory Sciences and supporting regulatory scientific advice, https://cordis.europa.eu/project/rcn/220223/factsheet/en, (November 2017 - present) • Active follow up and involvement in the Safe and Timely Access to Medinitative of the EU Commission on repurposing of old drug products in collaboration with the Bedjain Anticancer Fund (June 2018 - present) • Active involvement he pilot project on Simultaneous National Scientific Advice (SNSA) coordinated by the EU_IN with the Bedjain Anticancer Fund (June 2018 - present) • Active involvement as SNSA co_chair of the EU_IN in the Accelerating clinical Trails in the EU_GATE (EU_D_elivering an EU_clinical trails transformation initiative, introverse as SNSA co_chair of the EU_IN in the Accelerating clinical Trails in the EU_GATE of an industrial project proposal for basic research, submitted to the Institute for the Advancement of Scientific and Technolo (April 2022 - present) • Co_author of an industrial project proposal for basic research, submitted to the Institute for the Advancement of Scientific and Technolo (Industry (INT), (February 2000) • Co_author of a project proposal for basic research, submitted to the Fund of Scientific Research (FWO _ Vlaanderen), (Janual leader within the FAMHP for the project "Nuclear Project Institute for the Advancement of Scientific and Technology and

Memberships

• European Association of Nuclear Medicine (EANM), http://www.eanm.org, (May 2002 _ August 2004) • Society of Radiopharmaceutical Chemistry and Biology http://www.imaging. wustl.edu/RadsciChemistry/SRCB, (January 2002 _ August 2004) • International Research Group in Immunoscintigraphy and Immunother http://www.irist.org, (May 2003 _ August 2004) • VirRAD project member (Internet_based Virtual Radiopharmacy Learning Community), http://www.virrad.eu. no.: IST_2001_32291, (March 2002 _ August 2004) • Chemical_pharmaceutical expert recognized by the European Medicines Agency (EMA), London, UK (Octo present) • Belgian alternate member of the Paediatric Committee (PDCO) of the European Medicines Agency (EMA), (December 2007 - April 2008) • Belgian me Paediatric Committee formulation working group (PDCO FWG) of the European Medicines Agency (EMA), (December 2007 - June 2011) • Member of the Technic Radioisotypes (TRRI) of the RIZIV Institute, Brussels, regarding the common assessment for reimbursement of radiopharmaceuticals and radioisotopes, (March 2015 - Member of the high_level expert group on medical radioisotopes (HLG_MR) of the Nuclear Energy Agency (NEA) at the OECD March 2009 _ 2017) • Member of Innovation Offices Network" working group, coordinated by the Heads of Medicines Agencies (HMA) and the European Medicines Agency (EMA), (March 2015 - Member of the HMN4's "Medicines and device borderline and combination or products co_ordination working group (EMA), (March 2015 - Member of the HMDCG "Borderline & Classification working group (BCWG)" coordinated Device Coordination Group (MDCG) of the European Commission, (March 2018 - present) • Member of the MDCG "New Emerging Technologies working group (Intelligence & Digital Economy" coordinated by the Interministerial Economy Commission (IEC) of the Federal Public Service of Economy in collaboration with egworking Group on Competitiveness and Growth van HLG COMPGROW, Directorate A - Artificial Intelligence & Digital Industry and the Directorate_General for C Netw

Other Relevant Information

COLLABORATIONSHIPS: • Collaboration with the European Institute for Transuranium Elements (ITU, Karlsruhe, Germany) regarding the implemantation of alpha_radioimmunotherapy in Non_Hodgkin's Lymphoma as part of a European research project (September 1998 _ October 2001) • Collaboration with the Integergy Agency (IAEA, Vienna) regarding the development of regulatory guidance for clinical development of radiolabelled biologicals, (October 2005 – January 2001) • Collaboration with the FANC _ FAMHP working group on radiopharmaceuticals, in collaboration with the Federal Agency for Nuclear Control (FANC, Brussels), (April 2008 _ prese Collaboration with the European Clinical Trial Facilitation Group (CTFG) regarding the Eudralex Vol 10 Guidance document on "Harmonized requirements for non medicinal products in CTA submissions", (December 2008 – February 2009) • Collaboration with the Permanent Representation of Belgium to the European Unio Ministry of Health, the Federal Government Service of Economy, FANC, RIZIV and the Association of Imaging Producers and Equipment Suppliers (AIPES), EANN and the European Commission, regarding the international supply crisis for medical isotopes (March 2009 _ present) • Collaboration with the Scientific Institute (WIV), the Belgian Health Care Knowledge Center (KCE), the Federal Public Service Health, Food chain safety and environment (FOD VVVL), FANC and RIZIV escientific _ regulatory advice requests (April 2009 – present). • Collaboration with Flanders Investment Trade (FIT) regarding the provision of general and regulat foreign pharmaceutical and medical device / IVD companies exploring investments in Belgium (February 2015 – present). • Collaboration with the Belgian life schedithcare associations FlandersBio, BioWin and Pharma.Be regarding the implementation of national support mechanisms for SME's / academic research centers.

initiatives to stimulate innovation in the (pre)clinical development of medicinal products and healthcare products, (March 2016 – present). • Collaboration with the Working Group of the Belgian Biopharma platform and Federal Ministry of Health regarding the implementation of national innovation support mechanisms for the pharmaceutical industry, (June 2017 – present). • Collaboration with multiple disease_oriented patient organisations and umbrella organisations (eg. RadiOrg, Felatform, Wallonian Pattients Ligue) at national level and patient experts at EU level. • Collaboration with the European Patients' Academy (EUPATI Belgium) for training of disease_oriented patient organisations at national level. • Collaboration with the Korean Trade _ Investment Promotion Agency (KOTRA) regarding the general and regulatory guidance to Korean pharmaceutical and medical device / IVD companies exploring investments in Belgium (November 2018 – present). • with the Innovation Task Force (ITF) of the European Medicines Agency: Active participation in ITF meetings with Innovators regarding new innovative drug protechnologies used in clinical research, (May 2019 – Present) • Collaboration with the Belgian Patient Expert Centre (PEC) regarding patient engagement in early advice procedures related to clinical trials, (January 2022 – present) • Collaboration with the Wallonia Export and Investment Agency (AWEX) and the Brussels Agency (HUB.Brussels) regarding the provision of general and regulatory guidance to foreign pharmaceutical and medtech companies exploring investments in European Patient European Medicines Agencies (HMA) and Clinical Trials Coordination Group (CTCG) regarding the Clinical Trials in the EU (ACT EU) _ Delivering an EU clinical trials transformation initiative", (April 2022 – present)