

PERSONAL INFORMATION **Koenraad Norga**

WORK EXPERIENCE

- September 2019- Present **Chair, PDCO at EMA**
FAGG (Belgium)
- January 2012- Present **Head of Clinic, Paediatric Oncology**
Antwerp University Hospital (Belgium)
- October 2012- Present **Academic Faculty Member, Faculty of Medicine and Health Sciences**
Antwerp University (Belgium)
Teaching medical students: child and development / paediatrics
- March 2004-December 2011 **Adjunct Head of Clinic, Paediatric Oncology**
University Hospital Leuven (Belgium)
- October 2004-December 2011 **Academic Faculty Member, Faculty of Medicine**
University of Leuven (Belgium)
- January 2015- Present **Paediatric Residency Program Director**
Antwerp University (Belgium)
- January 2011-September 2019 **PDCO member (Belgium), EMA**
FAGG (Belgium)
(vice-chair 11/2013 - 09/2019)
- January 2016-October 2020 **CHMP co-opted member, EMA**
FAGG (Belgium)
- January 2018-September 2019 **SAWP member (nominated by PDCO), EMA**
FAGG (Belgium)
- January 2016- Present **additional paediatric expert, Oncology Working Party, EMA**
FAGG (Belgium)

EDUCATION AND TRAINING

- August 1999-February 2004 **PhD, Molecular and Human Genetics**
Baylor College of Medicine (United States)
Identification of neurodevelopment genes through quantitative trait analysis (advisor: H.Bellen)
- July 1998-September 2001 **Clinical and Research Fellowship Pediatric Hematology and Oncology**
Baylor College of Medicine and Texas Children's Hospital (United States)
- July 1995-June 1998 **Internship and Residency, Pediatrics**
Harvard Medical School and Boston Children's Hospital (United States)

September 1993-June 1995	Research Fellow, Pediatric Oncology Dana Farber Cancer Institute, Harvard Medical School (United States)
October 1986-June 1993	Doctor in de Genees-, Heel-, en Verloskunde (Medical Doctor) & Speciaal Baccalaureaat Wijsbegeerte (BA, Philosophy) University of Leuven (Belgium)
2010-	European Health Leadership Program INSEAD (France)
2008-	Clinical Trial Statistics for Non-Statisticians EORTC (Belgium)
October 1987-October 1989	Speciaal Baccalaureaat Wijsbegeerte (BA, Philosophy) University of Leuven (Belgium)

ADDITIONAL INFORMATION

Expertise	paediatric oncology, pharmacology, developmental biology, genetics, translational medicine, regulatory aspects of paediatric drug development
Publications	<ol style="list-style-type: none"> 1. Van Ranst M., Norga K., Masure S., Proost P., Vandekerckhove Ph., Auwerx J., Vandamme J., Opendakker G.: The cytokine-protease connection: identification of a 96 kD THP-1 gelatinase and regulation by interleukin-1 and cytokine inducers. <i>Cytokine</i> 3, 231-239, 1991. 2. Norga K., Breivik N., Buyse G., Casaer P. : Aicardi syndrome, a rare cause of infantile spasms. <i>Tijdschrift voor Kindergeneeskunde</i> 62, 220-223, 1994. 3. Norga K., Pless M., Stanulla M., TePas E.C., Mathey-Prevot B.: Multiple transcription start sites and 5 alternate splicing of murine Il-3 receptor b-chain transcripts. <i>Bioch. Biophys. Res. Comm.</i> 205, 886-892, 1994. 4. Norga K., Paemen L., Masure S. e.a. : Prevention of acute autoimmune encephalomyelitis and abrogation of relapses in murine models of multiple sclerosis by the protease inhibitor D-penicillamine. <i>Inflamm. Res.</i> 44, 529-534, 1995. 5. Norga K., Grillet B., Masure S., Paemen L., Opendakker G. : Human gelatinase B, a marker enzyme in rheumatoid arthritis, is inhibited by D-penicillamine: anti-rheumatic activity by protease inhibition. <i>Clinical Rheumatology</i> 15, 31-34, 1996. 6. Paemen L., Martens E., Norga K., e.a.: The gelatinase inhibitory activity of tetracyclines and chemically modified tetracycline analogues as measured by a novel microtiter assay for inhibitors. <i>Bioch. Pharm.</i> 52, 105-111, 1996. 7. Opendakker G., Paemen L., Norga K., Masure S.: Proteinase inhibition in invasive cancer therapy: four control levels of matrix degradation (Letter to the Editor). <i>Int. J. Cancer</i> 70, 628-630, 1997. 8. Pless M., Norga K., Carroll M., DAndrea A.D., Mathey-Prevot B.: Receptors that induce erythroid differentiation of Ba/F3 cells: structural requirements and effect on STAT5 binding. <i>Blood</i> 89, 3175-3185, 1997. 9. Wong JC, Alon N, Norga K, Krut FA, Youssoufian H, Buchwald M.: Cloning and analysis of the mouse Fanconi anemia group A cDNA and an overlapping penta zinc finger cDNA. <i>Genomics</i> 67, 273-83, 2000. 10. Jafar-Nejad H, Norga K, Bellen H: Numb: "Adapting" Notch for endocytosis. <i>Dev Cell</i> 3, 155-156, 2002. 11. Norga K, Gurganus MC, Dilda CL, Yamamoto A, Lyman RF, Patel PH, Mackay TF, Bellen HJ :Quantitative analysis of bristle number in Drosophila mutants identifies genes involved in neural development. <i>Curr Biol</i> 13:1388-1397, 2003. 12.Zhai RG, Hiesinger PR, Koh T-W, Verstreken P, Schulze K, Cao Y, Jafar-Nejad H, Norga K, Pan H, Bayat V, Greenbaum M, Bellen HJ: Mapping Drosophila Mutations with Molecularly Mapped P-elements. <i>Proc Natl Acad Sci U S A</i> 100:10860-5, 2003. 13.Harison ST, Yamamoto AH, Fanara JJ, Norga K, Mackay TFC: Quantitative trait loci affecting starvation resistance in Drosophila melanogaster. <i>Genetics</i> 166: 1807-1823, 2004

14. Lim J, Norga K, Chen Z, Choi KW. Control of planar cell polarity by interaction of DWnt4 and four-jointed. *Genesis* 2005 Jul;42(3):150-61
15. Dermaut B*, Norga K*, Kania A, Verstreken P, Pan H, Zhou Y, Callaerts P, Bellen HJ. Aberrant lysosomal carbohydrate storage accompanies endocytic defects and neurodegeneration in *Drosophila* benchwarmer. *J Cell Biol* 170(1):127-39, 2005. (*equal contribution).
16. Rollmann SM, Yamamoto A, Goossens T, Zwarts L, Callaerts-Vegh Z, Callaerts P, Norga K, Mackay TF, Anholt RR. The Early Developmental Gene Semaphorin 5c Contributes to Olfactory Behavior in Adult *Drosophila*. *Genetics* 2007 Apr 15
17. Laridon B, Callaerts P, Norga K. Embryonic expression patterns of *Drosophila* ACS family genes related to the human sialin gene. *Gene Expr Patterns* 2008 Apr;8(4):275-83.
18. Spasi MR, Callaerts P, Norga KK. *Drosophila* alicorn is a neuronal maintenance factor protecting against activity-induced retinal degeneration. *J Neurosci* 2008 Jun 18;28(25):6419-29.
19. Rollmann SM, Zwarts L, Edwards AC, Yamamoto A, Callaerts P, Norga K, Mackay TF, Anholt RR. Pleiotropic effects of *Drosophila* neuralized on complex behaviors and brain structure. *Genetics* 2008 Jul;179(3):1327-36.
20. Yamamoto A, Zwarts L, Callaerts P, Norga K, Mackay TF, Anholt RR. Neurogenetic networks for startle-induced locomotion in *Drosophila melanogaster*. *Proc Natl Acad Sci U S A* 2008 Aug 26;105(34):12393-8.
21. Mefford HC, Sharp AJ, Baker C, Itsara A, Jiang Z, Buysse K, Huang S, Maloney VK, Crolla JA, Baralle D, Collins A, Mercer C, Norga K, de Ravel T, Devriendt K, Bongers EM, de Leeuw N, Reardon W, Gimelli S, Bena F, Hennekam RC, Male A, Gaunt L, Clayton-Smith J, Simonic I, Park SM, Mehta SG, Nik-Zainal S, Woods CG, Firth HV, Parkin G, Fichera M, Reitano S, Lo Giudice M, Li KE, Casuga I, Broomer A, Conrad B, Schwerzmann M, Räber L, Gallati S, Striano P, Coppola A, Tolmie JL, Tobias ES, Lilley C, Armengol L, Spyschaert Y, Verloo P, De Coene A, Goossens L, Mortier G, Speleman F, van Binsbergen E, Nelen MR, Hochstenbach R, Poot M, Gallagher L, Gill M, McClellan J, King MC, Regan R, Skinner C, Stevenson RE, Antonarakis SE, Chen C, Estivill X, Menten B, Gimelli G, Gribble S, Schwartz S, Sutcliffe JS, Walsh T, Knight SJ, Sebat J, Romano C, Schwartz CE, Veltman JA, de Vries BB, Vermeesch JR, Barber JC, Willatt L, Tassabehji M, Eichler EE. Recurrent rearrangements of chromosome 1q21.1 and variable pediatric phenotypes. *N Engl J Med*. 2008 Oct 16;359(16):1685-99.
22. Spasic MR, Callaerts P, Norga KK. AMP-Activated Protein Kinase (AMPK) Molecular Crossroad for Metabolic Control and Survival of Neurons. *Neuroscientist* 2009 Apr 9.
23. Storkebaum E, Leitão-Gonçalves R, Godenschwege T, Nangle L, Mejia M, Bosmans I, Ooms T, Jacobs A, Van Dijck P, Yang XL, Schimmel P, Norga K, Timmerman V, Callaerts P, Jordanova A. Dominant mutations in the tyrosyl-tRNA synthetase gene recapitulate in *Drosophila* features of human Charcot-Marie-Tooth neuropathy. *Proc Natl Acad Sci U S A* 2009 Jul 14;106(28):11782-7.
24. Poels J, Spasi MR, Callaerts P, Norga KK. Expanding roles for AMP-activated protein kinase in neuronal survival and autophagy. *Bioessays* 2009 Sep;31(9):944-5.
25. Poels J, Spasi MR, Callaerts P, Norga KK An appetite for destruction: from self-eating to cell cannibalism as a neuronal survival strategy. *Autophagy*. 2012 Sep;8(9):1401-3.
26. Poels J, Spasi MR, Gistelinc M, Mutert J, Schellens A, Callaerts P, Norga KK Autophagy and phagocytosis-like cell cannibalism exert opposing effects on cellular survival during metabolic stress. *Cell Death Differ*. 2012 Oct;19(10):1590-601.
27. Ghillebert R, Swinnen E, Wen J, Vandesteene L, Ramon M, Norga K, Rolland F, Winderickx J. The AMPK/SNF1/SnRK1 fuel gauge and energy regulator: structure, function and regulation. *FEBS J*. 2011 Nov;278(21):3978-90.
28. Norga KK. Pediatric oncology for the general pediatrician: introduction to the Educational series. *Eur J Pediatr*. 2011 Feb;170(2):253-5
29. Rihani A, Van Maerken T, De Wilde B, Zeka F, Laureys G, Norga K, Tonini GP, Coco S, Versteeg R, Noguera R, Schulte JH, Eggert A, Stallings RL, Speleman F, Vandesompele J. Lack of association between MDM2 promoter SNP309 and clinical outcome in patients with neuroblastoma. *Pediatr Blood Cancer*. 2014 Jan 4.
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31. Herold R, Saint-Raymond A, Norga K. Too Few Medicines for Children With Cancer. *JAMA Pediatr*. 2014 Jun 1;168(6):583.

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38. Ecker A, Mariz S, Naumann-Winter F, Norga K, Barisic I, Girard T, Tomasi P, Mentzer D, Sepodes B. Comparative analysis of the scope of European Union paediatric investigation plans with corresponding orphan designations. *Arch Dis Child*. 2018 May;103(5):427-430
39. Gaspar N, Marshall LV, Binner D, Herold R, Rousseau R, Blanc P, Capdeville R, Carleer J, Copland C, Kerloeguen Y, Norga K, Pacaud L, Sevaux MA, Spadoni C, Sterba J, Ligas F, Taube T, Uttenreuther-Fischer M, Chioato S, O'Connell MA, Geoerger B, Blay JY, Soria JC, Kaye S, Wulff B, Brugières L, Vassal G, Pearson AD; Members of Working Group 1 of the Paediatric Platform of ACCELERATE. Joint adolescent-adult early phase clinical trials to improve access to new drugs for adolescents with cancer: proposals from the multi-stakeholder platform-ACCELERATE. *Ann Oncol*. 2018 Mar 1;29(3):766-771.
40. Pearson ADJ, Scobie N, Norga K, Ligas F, Chiodin D, Burke A, Minard-Colin V, Adamson P, Marshall LV, Balakumaran A, Benettaib B, Bhargava P, Bollard CM, Bolotin E, Bomken S, Buechner J, Burkhardt B, Caron H, Copland C, Demolis P, Egorov A, Farhan M, Zugmaier G, Gross T, Horton-Taylor D, Klapper W, Lesa G, Marcus R, Miles RR, Nottage K, Pacaud L, Ricafort R, Schrappe M, Sterba J, Vezan R, Weiner S, Kim SY, Reaman G, Vassal G. ACCELERATE and European Medicine Agency Paediatric Strategy Forum for medicinal product development for mature B-cell malignancies in children. *Eur J Cancer*. 2019 Mar;110:74-85.
41. Van Schoors M, Loeyts T, Goubert L, Berghmans G, Ooms B, Lemiere J, Norga K, Verhofstadt LL. Couples Dealing With Pediatric Blood Cancer: A Study on the Role of Dyadic Coping. *Front Psychol*. 2019 Feb 27;10:402.
42. Van Schoors M, De Paepe AL, Norga K, Cosyns V, Morren H, Vercruyse T, Goubert L, Verhofstadt LL. Family Members Dealing With Childhood Cancer: A Study on the Role of Family Functioning and Cancer Appraisal. *Front Psychol*. 2019 Jun 19;10:1405.
43. de Bruijn S, Anguille S, Verlooy J, Smits EL, van Tendeloo VF, de Laere M, Norga K, Berneman ZN, Lion E. Dendritic Cell-Based and Other Vaccination Strategies for Pediatric Cancer. *Cancers (Basel)*. 2019 Sep 19;11(9).
44. Van Schoors M, De Paepe AL, Lemiere J, Morez A, Norga K, Lambrecht K, Goubert L, Verhofstadt LL. Family Adjustment When Facing Pediatric Cancer: The Role of Parental Psychological Flexibility, Dyadic Coping, and Network Support. *Front Psychol*. 2019 Dec 10;10:2740.

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46. Mondelaers V, Ferster A, Uyttebroeck A, Brichard B, van der Werff Ten Bosch J, Norga K, Francotte N, Piette C, Vandemeulebroecke K, Verbeke C, Schmidt S, Benoit Y, Lammens T, De Moerloose B. Prospective, real-time monitoring of pegylated Escherichia coli and Erwinia asparaginase therapy in childhood acute lymphoblastic leukaemia and non-Hodgkin lymphoma in Belgium. *Br J Haematol*. 2020 Feb 14.
47. Papadouli I, Mueller-Berghaus J, Beuneu C, Ali S, Hofner B, Petavy F, Tzogani K, Miermont A, Norga K, Kholmanskikh O, Leest T, Schuessler-Lenz M, Salmonson T, Gisselbrecht C, Garcia JL, Pignatti F. EMA Review of Axicabtagene Ciloleucel (Yescarta) for the Treatment of Diffuse Large B-Cell Lymphoma. *Oncologist*. 2020 Apr 27;25(10):894-90
48. Karres D, Lesa G, Ligas F, Annunen P, van Dartel M, Demolis P, Galluzzo S, Herold R, van Crieckingen OK, Stoyanova-Beninska V, Norga K. Can a Multistakeholder Prioritization Structure Support Regulatory Decision Making? A Review of Pediatric Oncology Strategy Forums Reflecting on Challenges and Opportunities of this Concept. *Clin Pharmacol Ther*. 2020 Sep;108(3):553-556
49. Pearson ADJ, Zwaan CM, Kolb EA, Karres D, Guillot J, Kim SY, Marshall L, Tasian SK, Smith M, Cooper T, Adamson PC, Barry E, Benettaib B, Binlich F, Borgman A, Brivio E, Capdeville R, Delgado D, Faller D, Fogelstrand L, Fraenkel PG, Hasle H, Heenen D, Kaspers G, Kieran M, Klusmann JH, Lesa G, Ligas F, Mappa S, Mohamed H, Moore A, Morris J, Nottage K, Reinhardt D, Scobie N, Simko S, Winkler T, Norga K, Reaman G, Vassal G. Paediatric Strategy Forum for medicinal product development for acute myeloid leukaemia in children and adolescents: ACCELERATE in collaboration with the European Medicines Agency with participation of the Food and Drug Administration. *Eur J Cancer*. 2020 Sep;136:116-129
50. Reaman G, Karres D, Ligas F, Lesa G, Casey D, Ehrlich L, Norga K, Pazdur R. Accelerating the Global Development of Pediatric Cancer Drugs: A Call to Coordinate the Submissions of Pediatric Investigation Plans and Pediatric Study Plans to the European Medicines Agency and US Food and Drug Administration. *J Clin Oncol*. 2020 Sep 18;JCO2002152
51. Pearson AD, Stegmaier K, Bourdeaut F, Reaman G, Heenen D, Meyers ML, Armstrong SA, Brown P, De Carvalho D, Jabado N, Marshall L, Rivera M, Smith M, Adamson PC, Barone A, Baumann C, Blackman S, Buenger V, Donoghue M, Duncan AD, Fox E, Gadbar B, Hattersley M, Ho P, Jacobs I, Kelly MJ, Kieran M, Lesa G, Ligas F, Ludwinski D, McDonough J, Nikolova Z, Norga K, Senderowicz A, Taube T, Weiner S, Karres D, Vassal G. Paediatric Strategy Forum for medicinal product development of epigenetic modifiers for children: ACCELERATE in collaboration with the European Medicines Agency with participation of the Food and Drug Administration. *Eur J Cancer*. 2020 Nov;139:135-148

Projects Laboratory of Developmental Genetics, Flemish Institute of Biotechnology (VIB), associate group leader (2004-2008)

Memberships Licensing:
 Medical License Belgium (1993)
 ECFMG Certification (0-493-280-2) (1994)
 Massachusetts Training License (1995-1998)
 Texas Institutional Permit (1995-2001)
 Pediatric Board Certificate, American Board of Pediatrics (1998)
 Board Eligible Pediatric Hematology/Oncology, American Board of Pediatrics (2001)
 Erkend geneesheer-specialist kindergeneeskunde (certified paediatrician), Belgium (2004-)
 Bijzondere beroepsbekwaamheid pediatrie hematologie/oncologie (certified paediatric haematologist/oncologist), Belgium (2014-)
 Membership:

Vlaamse Vereniging Kindergeneeskunde, board member
Belgische Vereniging Kindergeneeskunde
Belgian Society Paediatric Hematology/Oncology (BSPHO), board member
International Society Pediatric Oncology-Europe (SIOP-E)
International Society Pediatric Oncology (SIOP)
Children's Oncology Group (COG), USA (International Associate Member)
Awards/Scholarships:
Fulbright Scholarship (1993-1995)
Belgian-American Educational Foundation Fellowship (1993-1994)
Frank Boas Scholarship Harvard University (1993)
D.Collen Research Fellowship (1994, 1999-2001)
Von L. Mayer Award, Children's Hospital, Boston (1997)
Prof. John J. Trentin Award for Academic Excellence, Baylor College of Medicine (2000)
Postdoctoral Fellowship for Physicians, Howard Hughes Medical Institute (2001-2004)
Senior Clinical Investigator, FWO-Flanders (2004-2008)
Return Mandate, Federal Science Policy, Belgium (2004-2006)
Marie Curie International Reintegration Grant, EU (2005-2007)

Other Relevant Information

European Medical Students' Association, founding member (1990)
International Doctoral School Biomedical Sciences, University of Leuven, co-founder / coordinator of the Molecular and Human Genetics Program / member of various committees / major doctoral thesis advisor (3 graduate students) (2005-2010)
Leuven Cancer Institute, Research Task Force, member (2006-2010)
Department of Woman and Child Health, University of Leuven, coordinator of research (2006-2008)
Commissie Tegemoetkoming Geneesmiddelen (Medicinal Product Reimbursement Committee), RIZIV-Belgium, member (2006-2008)
Medical Ethics Committee, University Hospitals Leuven, member (2007-2008)
Genomics Core Facility, University Hospitals Leuven, co-founder/member of scientific council (2007-2010)
Commission for Educational Exchange between the United States, Belgium and Luxembourg (Fulbright Commission), member of various selection committees (2008-2011)
Quality Improvement and Patient Safety Program, Children's Hospital, University Hospitals Leuven, chair (2008)
Leuven Network for Translational Medicine, coordinator (2008-2010)
Interface Valorisation Platform (IVAP) in Immunology and Infectious Diseases, University of Leuven, coordinator (2008-2010)
Biobank Board, University Hospitals Leuven, member (2009-2010)
Expert Group Translation and Technology, Biomedical Sciences Group, University of Leuven, chair (2009-2010)
Medical Ethics Committee, Antwerp University Hospital, Paediatric expert (2012-)
Indicator Task Force, Quality and Patient Safety Steering Committee, Antwerp University Hospital, chair (2014-2015)
Evaluation Committee Doctoral Studies, Faculty of Medicine and Health Sciences, Antwerp University, member (2012-2015)