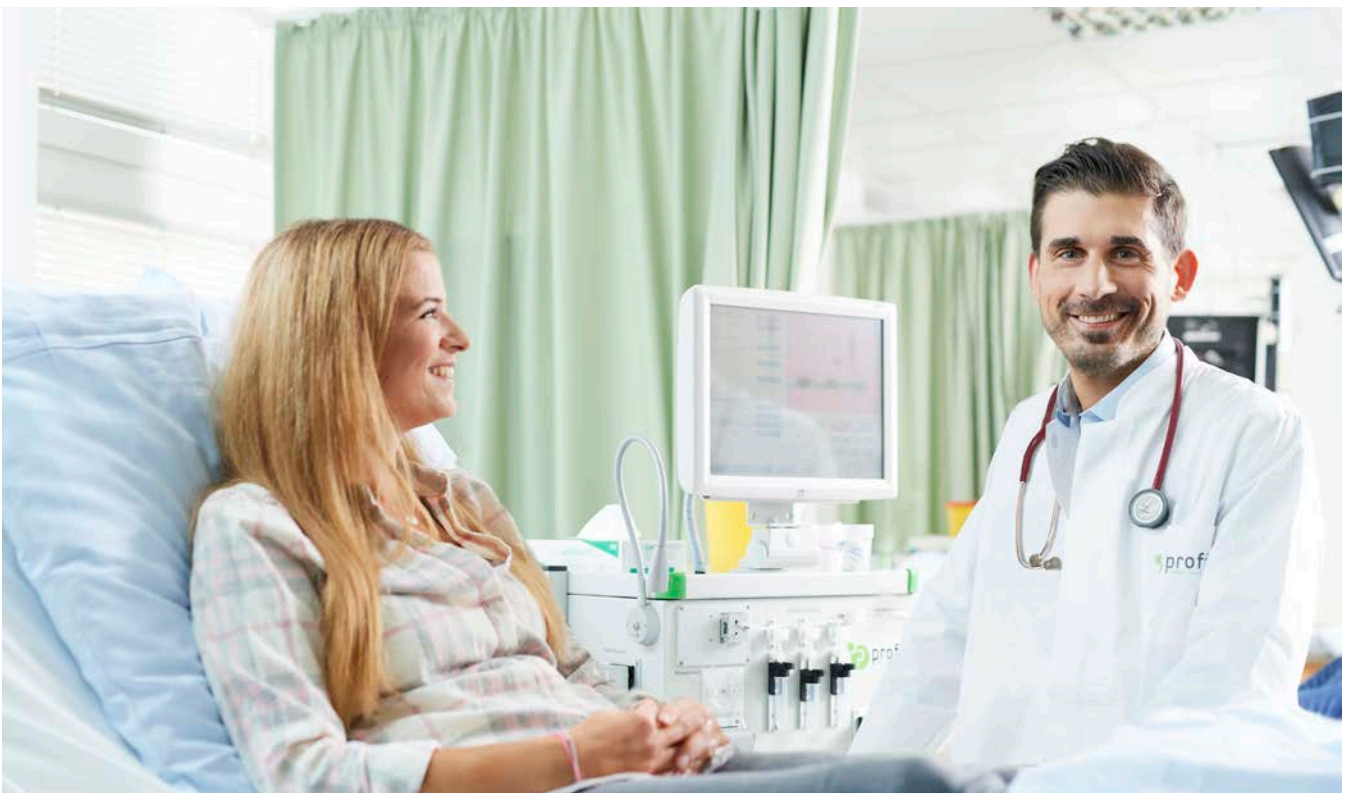




Science Report 2019



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Dr. Tim Heise
Lead Scientist
Chairman of the Board of Directors
Co-Founder of Profil

Preface

"Teamwork is the fuel that allows common people to attain uncommon results."

Albert Einstein
(1879-1955)

It is with pride, but also with humility, that I present the Profil Science Report 2019. We usually publish our Science Report in the first quarter of the following year, but what is usual in these times? On the other hand, what is more suited than the dramatic situation of a pandemic to demonstrate the value of science? Indeed, never have scientific achievements been followed so closely, and never before has scientific knowledge so quickly translated into the savings of many lives as in the past months.

The rising knowledge on the COVID-19 infection has been a time lapse of usual scientific procedures. Most of all, it illustrated that scientific knowledge gain is a work of many rather than just a few. Not only that nearly all publications contribute just little pieces of additional knowledge to the overall puzzle, there is also a large team behind the scientific work of each and every publication.

This is not only true for papers on COVID-19, but for all scientific topics. At Profil, we have tried for many years to contribute our tiny little piece of scientific papers to improve treatment

options for people with diabetes and related diseases as obesity and NAFLD/NASH. In the past year, Profil's scientific experts published 27 scientific papers (cumulated impact factor of nearly 150) and 56 scientific presentations at international meetings – all beautifully collected and summarised by Prof. Freimut Schliess who invested a lot of work and put his heart and soul into yet another impressive Science Report (in addition to contribution to our scientific papers himself). All these publications would not have been possible without the immense work and commitment of all our staff, not only study nurses, clamp technicians, lab personnel, investigators and many more in our clinics, but also all the hard-working people in Quality Assurance, Finance, IT and all the other logistic departments that establish the environment needed for high-quality research. Therefore, this Science Report illustrates the truth behind Albert Einstein's famous quote above: The steep and often painful path to additional (scientific) knowledge can only be surmounted by a well-functioning team whose members complement each other. At Profil, we are blessed with such a great team, and we are very grateful for the many contributions of all our staff to our scientific success.

While we (as a non-academic institute) are proud of our high scientific output, there is some concern that the current pandemic will overshadow all other research. Indeed, we have only received feedback from journals that the acceptance rate of publications not related to COVID-19 have dropped considerably. The huge interest in a potentially life-threatening pandemic illness is understandable, but we must not forget that many chronically ill people such as patients with diabetes have been struggled with coping with their disease for many years before (and will also for many years after) the pandemic. These people are in desperate need of our help, and we must not slow down our efforts to find better treatment options. This Science Report therefore is not only dedicated to the team at Profil, but foremost to all patients with diabetes who have to take care of their disease every single day of their lives – and still find the time and dedication to help us with their participation in our studies.



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Metrics

TABLE 1: TOTAL OUTPUT

	Count	Σ Impact Factors	Mean Impact Factor
Scientific Publications	27	149,35	5,53
Original Articles	17	115,93	6,82
Reviews	5	33,42	6,68
Letters/Comments	5	0,00	0,00
Scientific Congress Presentations	56	n/a	n/a
Orals	29	n/a	n/a
Poster	27	n/a	n/a
Advanced Trainings	29	n/a	n/a
Granted Research Consortia	2	n/a	n/a
Scientific Communication	32+	n/a	n/a
Webinars	2	n/a	n/a
Blogs	26	n/a	n/a
Media Reports	4+	n/a	n/a

TABLE 2: PROFIL SCIENTIST(S) FIRST/SENIOR AUTHOR

	Count	Σ Impact Factors	Mean Impact Factor
Scientific Publications	19	89,79	4,73
Original Articles	10	72,39	7,24
Reviews	4	17,40	6,68
Letters/Comments	5	0,00	0,00
Scientific Congress Presentations	41	n/a	n/a
Orals	24	n/a	n/a
Poster	17	n/a	n/a

TABLE 3: PUBLISHED STUDIES (PARTLY) OPERATED BY PROFIL

	Count	Σ Impact Factors	Mean Impact Factor
Scientific Publications	12	81,36	6,78
Original Articles	12	81,36	6,78
Reviews	n/a	n/a	n/a
Letters/Comments	n/a	n/a	n/a
Scientific Congress Presentations	45	n/a	n/a
Orals	20	n/a	n/a
Poster	25	n/a	n/a

**TABLE 4: PUBLISHED STUDIES (PARTLY) OPERATED BY PROFIL
+ PROFIL SCIENTIST(S) FIRST/SENIOR AUTHOR**

	Count	Σ Impact Factors	Mean Impact Factor
Scientific Publications	9	74,00	7,39
Original Articles	9	73,00	7,39
Reviews	n/a	n/a	n/a
Letters/Comments	n/a	n/a	n/a
Scientific Congress Presentations	32	n/a	n/a
Orals	16	n/a	n/a
Poster	16	n/a	n/a

Scientific Publications

Original Articles

1. Kapitza, C.,¹ Nosek, L., Schmider, W., Teichert, L., Nowotny, I.
Single-dose euglycemic clamp study demonstrating pharmacokinetic and pharmacodynamic similarity between SAR341402 insulin aspart and US- and EU-approved versions of insulin aspart in subjects with type 1 diabetes.
Diabetes Technol. Therap. 2019 Dec 30, doi:10.1089/dia.2019.0351.
IF(2019): 4,39
2. Parker, V.E.R., Robertson, D., Wang, T., Hornigold, D.C., Petrone, M., Cooper, A.T., Posch, M.G., Heise T., Plum-Mörschel, L., Heike, S., Klaus, B., Ambery, P.D., Meier, J.J., Hirshberg, B.
Efficacy, safety, and mechanistic insights of cotadutide, a dual receptor glucagon-like peptide-1 and glucagon agonist.
J. Clin. Endocrinol. Metab. 2019 Mar 1, doi:10.1210/clinem/dgz047.
IF(2019): 5,65
3. Meier, J.J., Menge, B.A., Schenker, N., Erdmann, S., Kahle-Stephan, M., Schliess F., Kapitza C., Nauck, M.A.
Effects of sequential treatment with lixisenatide, insulin glargine, or their combination on meal-related glycaemic excursions, insulin and glucagon secretion, and gastric emptying in patients with type 2 diabetes.
Diabetes Obes. Metab. 2019 Dec 3, doi:10.1111/dom.13935.
IF(2019): 5,90
4. Heise, T., Donnelly, C., Barve, A., Ankersen, M., Aubonnet, P.
Pharmacokinetic and pharmacodynamic bioequivalence of proposed biosimilar MYL1501D with US and EU insulin glargine formulations in patients with type 1 diabetes mellitus.
Diabetes Obes. Metab. 2019 Dec 15, doi:10.1111/dom.13919.
IF(2019): 5,90

¹ Underlined: authors from Profil

5. Benesch, C., Kuhlenkötter, M., Heise T.
Considering blood dilution improves the precision of continuous whole blood glucose measurements.
J. Diabetes Sci. Technol. 13(4):751-755, 2019
IF(2018): 3,32
6. Halberg, I.B., Lyby, K., Wassermann, K., Heise, T., Plum-Mörschel, L., Zijlstra, E.
The effect of food intake on the pharmacokinetics of oral basal insulin: a randomised crossover trial in healthy male subjects.
Clin. Pharmacokinet. 58(11):1497-1504, 2019
IF(2019): 4,92
7. Haahr, H., Pieber, T.R., Mathieu, C., Gondolf, T., Shiramoto, M., Erichsen, L., Heise, T.
Clinical pharmacology of fast-acting insulin aspart versus insulin aspart measured as free or total insulin aspart and the relation to anti-insulin aspart antibody levels in subjects with type 1 diabetes mellitus.
Clin. Pharmacokinet. 58(5):639-649, 2019
IF(2019): 4,92
8. Dovc, K., Boughton, C., Tauschmann, M., Thabit, H., Bally, L., Allen, J.M., Acerini, C.L., Arnolds, S., de Beaufort, C., Bergenstal, R.M., Campbell, F., Criego, A., Dunger, D.B., Elleri, D., Evans, M.L., Fröhlich-Reiterer, E., Hofer, S., Kapellen, T., Leelarathna, L., Pieber, T.R., Shah, V.N., Carlson, A.L., Bergenstal, R.M., Evans, M.L., Hovorka, R., AP@home04 and APCam11 consortia.
Young children have higher variability of insulin requirements: observations during hybrid closed-loop insulin delivery.
Diabetes Care 42(7):1344-1347, 2019
IF(2019): 16,02
9. Heise, T., Meiffren, G., Alluis, B., Seroussi, C., Ranson, A., Arrubla, J., Correia, J., Gaudier, M., Soula, O., Soula, R., DeVries, J.H., Klein, O., Bode B.
BioChaperone lispro versus faster aspart and insulin aspart in patients with type 1 diabetes using continuous subcutaneous insulin infusion: a randomized euglycemic clamp study.
Diabetes Obes. Metab. 21(4):1066-1070, 2019
IF(2019): 5,90

10. Klonoff, D.C., Evans, M.L., Lane, W., Kempe, H.P., Renard, E., DeVries, J.H., Graungaard, T., Hyseni, A., Gondolf, T., Battelino, T.
A randomized, multicentre trial evaluating the efficacy and safety of fast-acting insulin aspart in continuous subcutaneous insulin infusion in adults with type 1 diabetes (onset 5).
Diabetes Obes. Metab. 21(4):961-967, 2019
IF(2019): 5,90

11. Leelarathna, L., Thabit, H., Wilinska, M.E., Bally, L., Mader, J.K., Pieber, T.R., Benesch, C., Arnolds, S., Johnson, T., Heinemann, L., Hermanns, N., Evans, M.L., Hovorka, R.
Evaluating glucose control with a novel composite continuous glucose monitoring index.
J. Diabetes Sci. Technol. 14(2):277-283, 2019
IF(2018): 3,32

12. Meiffren G., Herbrand T., Anastassiadis E., Klein O., DeVries J.H., Heise T., Alluis B., Mégret C., Gaudier M., Soula O., Plum-Mörschel L.
Better glycaemic control with BioChaperone glargine lispro co-formulation than with insulin lispro Mix25 or separate glargine and lispro administrations after a test meal in people with type 2 diabetes.
Diabetes Obes. Metab. 21(7):1570-1575, 2019
IF(2019): 5,90

13. DeVries, J.H., Bailey, T.S., Bhargava, A., Gerety, G., Gumprecht, J., Heller, S., Lane, W., Wysham, C.H., Zinman, B., Bak, B.A., Hachmann-Nielsen, E., Philis-Tsimikas, A.
Day-to-day fasting self-monitored blood glucose variability is associated with risk of hypoglycaemia in insulin-treated patients with type 1 and type 2 diabetes: a post hoc analysis of the SWITCH Trials.
Diabetes Obes. Metab. 21(3):622–630, 2019
IF(2019): 5,90

14. Hövelmann, U., Braendholt, O.M., Mouritzen, U., Lamers, D., Kronshage, B., Heise, T.
Low doses of dasiglucagon consistently increase plasma glucose levels from hypoglycaemia and euglycaemia in people with type 1 diabetes mellitus.
Diabetes Obes. Metab. 21(3):601-610, 2019
IF(2019): 5,90

15. Al-Qaissi, A., Papageorgiou, M., Javed, Z., Heise, T., Rigby, A.S., Garrett, A.T., Hepburn, D., Kilpatrick, E.S., Atkin, S.L., Sathyapalan, T.
Environmental effects of ambient temperature and relative humidity on insulin pharmacodynamics in adults with type 1 diabetes mellitus.
Diabetes Obes. Metab. 21(3):569-574, 2019
IF(2019): 5,90
16. Halberg, I.B., Lyby, K., Wassermann, K., Heise, T., Zijlstra, E., Plum-Mörschel, L.
Efficacy and safety of oral basal insulin versus subcutaneous insulin glargine in type 2 diabetes: a randomised, double-blind, phase 2 trial.
Lancet Diabetes Endocrinol. 7(3):179-188, 2019
IF(2019): 25,34
17. Bücken, B., Wilm, S., Arnolds, S., Icks, A., Lachmann, N., Verket, M., Spörkel, O.
Welche Präferenzen haben Menschen mit Diabetes Mellitus in Bezug auf die Diabetesforschung? – Eine qualitative Studie.
Diabetologie und Stoffwechsel 14(01):56-63, 2019
IF(2018): 0,85

Reviews

18. Schliess, F., Heise, T., Benesch, C., Mianowska, B., Stegbauer, C., Broge, B., Gillard, P., Binkley, G., Crône, V., Carlier, S., Delval, C., Petkov, A., Beck, J.P., Lodwig, V., Gurdala, M., Szecsenyi, J., Rosenmüller, M., Cypryk, K., Mathieu, C., Renard, E., Heinemann, L.
Artificial pancreas systems for people with type 2 diabetes: conception and design of the European CLOSE project.
J. Diabetes Sci. Technol. 13(2):261-267, 2019
IF(2018): 3,32

19. Schloot, N.C., Hood, R.C., Corrigan, S.M., Panek, R.L., Heise, T.
Concentrated insulins in current clinical practice.
Diabetes Res. Clin. Pract. 148:93-101, 2019
IF(2019): 3,26

20. Battelino, T., Danne, T., Bergenstal, R.M., Amiel, S.A., Beck, R., Biester, T., Bosi, E., Buckingham, B.A., Cefalu, W.T., Close, K.L., Cobelli, C., Dassau, E., DeVries, J.H., Donaghue, K.C., Dovc, K., Doyle, F.J. 3rd, Garg, S., Grunberger, G., Heller, S., Heinemann, L., Hirsch, I.B., Hovorka, R., Jia, W., Kordonouri, O., Kovatchev, B., Kowalski, A., Laffel L, Levine, B., Mayorov, A., Mathieu, C., Murphy, H.R., Nimri, R., Nørgaard, K., Parkin, C.G., Renard, E., Rodbard, D., Saboo, B., Schatz, D., Stoner, K., Urakami, T., Weinzimer, S.A., Phillip, M.
Clinical targets for continuous glucose monitoring data interpretation: recommendations from the international consensus on time in range.
Diabetes Care 42(8):1593-1603, 2019
IF(2019): 16,02

21. Hahr H., Heise T.
Fast-acting insulin aspart: a review of its pharmacokinetic and pharmacodynamic properties and the clinical consequences.
Clinical Pharmacokinetics. doi: 10.1007/s40262-019-00834-5, 2019
IF(2019): 4,92

22. Evans, M., Ceriello, A., Danne, T., De Block, C., DeVries, J.H., Lind, M., Mathieu, C., Nørgaard, K., Renard, E., Wilmot, E.G.
Use of fast-acting insulin aspart in insulin pump therapy in clinical practice.
Diabetes Obes. Metab. 21(9):2039-2047, 2019
IF(2019): 5,90

Letters / Comments

23. Schliess, F.
iPDM goes Europe: the impact on diabetes and patient care.
Open Access Government. ISSN 2516-3817:144-145, October 2019
IF: -
24. Schliess, F.
Clinical contract research: building the digital bridge between clinical research and clinical care.
Open Access Government. ISSN 2516-3817:118-118, August 2019
IF: -
25. Schliess, F.
Digital solutions in the management of diabetes.
EIT Health Views. May 2019
IF: -
26. Schliess, F.
A life- and disease course approach to health protection and chronic care.
Open Access Government. ISSN 2516:3817:80-18, April, 2019
IF: -
27. Schliess, F.
Artificial pancreas systems in type 2 diabetes.
Open Access Government. ISSN 2516:3817:38-39, January, 2019
IF: -

Scientific Presentations

Oral Presentations

EIT Health Summit 2019. Defining unmet need – how much does it matter? Palais Brogniart, Paris, France, December 2 – 3, 2019

28. Schliess, F.
Automated glucose control at home for people with chronic disease.

Diabetes support group Aachen. Aachen, Germany, December 2, 2019

29. Arnolds, S.
Closed-loop metabolic control by means of artificial pancreas systems – the state of the art.

4th World Congress on Clinical Trials in Diabetes. Amsterdam, Netherlands, November 26 – 27, 2019

30. DeVries, J.H.
Marketed insulins: what can be achieved?

EMBO Workshop Precision Health: Molecular Basis, Technology and Digital Health. Heidelberg, Germany, November 13 – 16, 2019

31. Jones, A., Bardram, J., Baekgaard, P., Skinner, T., Vrangbaek, K., Norgaard, K., Glümer, C., Schliess, F., Wang-Sattler, R., Holle, R., Laxy, M., Kownatka, D.
Enhancing, implementing and scaling integrated personalised diabetes management to improve outcomes for people with diabetes.
32. Jones, A., Bardram, J., Baekgaard, P., Skinner, T., Vrangbaek, K., Norgaard, K., Glümer, C., Schliess, F., Wang-Sattler, R., Holle, R., Laxy, M., Kownatka, D.
Integrated personalized diabetes management goes Europe: adding value to diabetes care through digital innovation and integrated care.

19th Annual Diabetes Technology Meeting (DTM). Bethesda, USA, November 14-16, 2019

33. Heise, T.
Future insulins: gazing into a crystal ball.

EIT Health Germany Annual Symposium. Roche Diagnostics, Open Campus, Mannheim, Germany, November 5, 2019

34. Schliess, F., Parmentier, T., de Marco, S., Dopierala, C., Cięciak, K., Frieriep, U., Jacobsen, M., Schütt, K., Stegbauer, C., Hentschel, A., Szecsenyi, J., Lemaire, M., Müller-Wieland, D., Marx, N., Rüling, C.-C., Plum-Mörschel, L., Heise, T., Cinquin, P.
Real-world cardiorespiratory health monitoring for clinical contract research and telecardiology.
35. de Marco, S., Alexandersson, J., Schliess, F., Rüling, C.-C., Girenko, A., Gründel, C., Schubert, C., Münzenmayer, C., Norgall, T. Makutzik, E.-M., Harten, A.
Roundtable discussion: Telemedical monitoring of people with heart disease.
36. Alexandersson, J., Girenko, K., Rüling, C.-C., de Marco, S., Schliess, F., Stainer-Hochgatterer, A., Wassertheurer, S., Gensuinne, P., Ashraf, W., Gründel, C., Bansal, A., Rode-Schubert, C., Münzenmayer, C., Tran, S., Eggert-Griscelli, R., Chehadé, M.
Roundtable discussion: The AIWatch case: continuous cardiac monitoring on the basis of multimodal biosignals – challenges and opportunities.

EIT Health Think Tank. Federal state representation Baden-Württemberg, Berlin, Germany, October 10, 2019

37. Børlum Kristensen, F., Ehlers, A., Danner, M., Mandler, M., Müller-Wieland, D., Pfaff, H., Sebhatu, J., Schliess, F., Sonntag, K., Stork, W., Vogt, A.
Optimizing innovation pathways: future proofing for success.

17th Düsseldorf Diabetes day. Düsseldorf chamber of trade. Düsseldorf, Germany, September 7, 2019

38. Arnolds, S.
New research approaches to innovation in diabetes.

55th European Association for the study of diabetes (EASD) Annual Meeting. Barcelona, Spain, September 16 – 20, 2019

39. Ólafsdóttir, A.F., Bolinder, J., Heise, T., Polonsky, W., Ekelund, M., Wijkman, M., Pivodic, A., Schwarcz, E., Nyström, T., Hellman, J., Hirsch, I.B., Lind, M.
Majority of persons with type 1 diabetes on multiple daily insulin injections benefit from continuous glucose monitoring.
Diabetologia 62(Suppl 1):A41, 2019

40. Meiffren G., Andersen G., Seroussi C., Ranson A., Famulla S., Gaudier M., Soula R., Soula O., Eloy R., Heise T., Chan Y.P., Charvet R., DeVries J.H. ADO09, a co-formulation of the amylin-analogue pramlintide and the A21G human insulin analogue, lowers postprandial blood glucose versus insulin lispro in type 1 diabetes.
Diabetologia 62(Suppl 1):A109, 2019
41. Robertson, D., Parker, V.E., Ambery, P.D., Petrone, M., Wang, T., Heise, T., Plum-Mörschel, L., Jermutus, L., Hirshberg, B., Meier J.J. Cotadutide (MEDI0382) promotes dose-dependent increases in gastric emptying time.
Diabetologia 62 (Suppl 1):A111, 2019
42. Heise, T., Linnebjerg, H., Cao, D., Coutant, D.E., Smith LaBell, E., Reddy, S., Bowerman, S., Zijlstra, E., Kapitza, C., Bue-Vallesky, J.M., Zhang, Q., Leohr, J.K. Ultra rapid lispro (URLi) lowers postprandial glucose (PPG) and more closely matches normal physiological glucose response compared to other rapid insulin analogues.
Diabetologia 62 (Suppl 1): A182, 2019

Regional Diabetes Expert Summit. Kolkata, India, August 4, 2019

43. Zijlstra, E.
Ultrafast-acting insulins: a left shift in Pharmacology.
44. Ghosal, S., Fulcher, G., Zijlstra, E.
Moderating the Session on the pathophysiology and management of type 2 diabetes.
45. Ghosal, S., Fulcher, G., Zijlstra, E., Downie, M., Kumar, A., Sinha, B.
Panel discussion on the initiation of insulin therapy in type 2 diabetes.
46. Downie, M., Zijlstra, E.
Moderating the session on insulin therapy intensification.

American Diabetes Association (ADA) 79th Scientific Sessions. San Francisco, USA. June 7 – 11, 2019

47. Meiffren, G., Seroussi, C., Ranson, A., Charvet, R., Gaudier, M., Andersen, G., Zijlstra, E., DeVries, J.H., Heise, T., Soula, R., Soula, O.
BioChaperone pramlintide insulin (BCPramIns), a new co-formulation of pramlintide (PRAM) and human insulin (INS), improves postprandial blood glucose (BG) vs. both separate injections of PRAM+INS and insulin lispro (LIS) in subjects with T1D.
Diabetes 68 (Suppl. 1):150-OR, 2019

48. Pieber, T.R., Hövelmann, U., Willard, J., Plum-Mörschel, L., Mouritzen, U., Tehranchi, R., Aronson, R.
Phase 3 results for dasiglucagon as a fast and effective treatment for severe hypoglycemia.
Diabetes 68 (Suppl. 1):286-OR, 2019

55th Annual Conference of the German Diabetes Association (DDG). Berlin, Germany, May 29 – June 1, 2019

49. Heise, T.
Oral and liver-specific insulins

Physician quality circle diabetes. Neuss, Germany, May 15, 2019

50. Arnolds, S.
Clinical research for new drugs – what’s in the pipeline for persons with diabetes?

85th Annual Conference of the German Cardiology Association (DGK), Mannheim, Germany, April 24 – 27, 2019

51. Herbrand, T., Coester, H.V., DeVries, J.H., Heiss, C., Heise, T., Kelm, M., Sansone R.
Better assessment of flow-mediated dilation (FMD) by measuring real dilatatory peak time.
Clin. Res. Cardiol. 108(Suppl 1), 2019.

Type 2 diabetes support group Essen. Essen, Germany, March 15, 2019

52. Arnolds, S.
Profil – Clinical research for a better life with diabetes

12th International Conference on Advanced Technologies and Treatments for Diabetes (ATTD). Berlin, Germany, February 20 – 23, 2019

53. Heise, T.
Smart Insulins
Diabetes Technol. Ther. 21(S1):A-1, 2019
54. DeVries, J.H.
Session chair: CGM for hypoglycemia-prone patients: what patients do with CGM data and what they should do.
Diabetes Technol. Ther. 21(S1):A-10, 2019

55. DeVries, J.H., Zijlstra, E.
Session chairs: New avenues in protein drugs for diabetes.
Diabetes Technol. Ther. 21(S1):A-1, 2019
56. Kazda, C., Leohr, J., Liu, R., Hardy, T., Reddy, S., Chua, S., Hövelmann U., Kapitza, C.
Ultra-rapid lispro (URLI) shows faster insulin absorption and improved postprandial glucose lowering vs lispro during insulin pump use in patients with T1D.
Diabetes Technol. Ther. 21(S1):A-29, 2019
57. Meiffren, G., Klein, O., Seroussi, C., Ranson, A., Arrubla, J., Correia, J., Gaudier, M., Soula, O., Soula, R., Alluis, B., Bode, B.W., Heise T.
The ultra-rapid insulin biochaperone lispro bolused by insulin pump shows favourable pharmacodynamics and pharmacokinetics vs faster aspart and insulin aspart.
Diabetes Technol. Ther. 21(S1):A-32, 2019
58. Suico, J., Hövelmann, U., Zhang, S., Shen, T., Bergman, B., Sherr, J., Zijlstra, E., Frier, B., Plum-Mörschel, L.
Nasal glucagon: a viable alternative to treat insulin-induced hypoglycemia in adults with type 1 diabetes.
Diabetes Technol. Ther. 21(S1):A-33, 2019

ATTD Industry Sessions. Berlin, Germany, February 22, 2019

59. DeVries, J.H.
Technological advancements in diabetes care.

Type 1 diabetes day. Berlin, Germany, January 27, 2019

60. Herbrand, T.
How to become part of a clinical trial.

Poster Presentations

19th Annual Diabetes Technology Meeting (DTM). Bethesda, USA, November 14 – 16, 2019

61. Benesch, C., Kuhlenkötter, M., Nosek, L., Heise, T.
New glucose clamp algorithm improves clamp quality with rapid-acting insulins.
J. Diabetes Sci. Technol. 14(2):A-8, 2020
62. Kuhlenkötter, M., Benesch, C., Heckermann, S.
Control deviation is not suited as a clamp quality parameter.
J. Diabetes Sci. Technol. 14 (2):A-59, 2020
63. Stoffel, M., Kuhlenkötter, M., Benesch, C., Heckermann, S., Zijlstra, E., Heise, T., DeVries, J.H.
A novel method for determination of pharmacodynamic onset of prandial insulin action
J. Diabetes Sci. Technol. 14(2):A-108, 2020
64. Zijlstra, E., Klein, O., Sievers, F., Porter, L., Bueche, B., Kuo, M., Le, T., Stedman B.J., Rhodes M., Patton J.S.
Dance 501 inhaled human insulin: linear dose response in patients with type 1 diabetes.
J. Diabetes Sci. Technol. 14(2):A-126, 2020
65. Zijlstra, E., Plum-Mörschel, L., Ermer, M., Klein, O., Porter L., Bueche B., Kuo M., Le, T., Stedman, B.J., Rhodes, M., Patton J.S.
Faster absorption and greater early insulin action of Dance 501 inhaled human insulin vs. s.c. insulin lispro in patients with type 2 diabetes.
J. Diabetes Sci. Technol. 14 (2):A-127, 2020

Telemedicine workshop for EIT Health partners and supported startups. Telemedicine Centre RWTH Aachen, Aachen, Germany, September 24, 2019

66. Jacobsen, M., Müller-Wieland, D., Marx, N., Parmentier, T., Cinquin, P., Heckermann, S., Heise, T., Schliess, F.
RealWorld4Clinic.

55th European Association for the Study of Diabetes (EASD) Annual Meeting. Barcelona, Spain, September 16 – 20, 2019

67. Leohr, J., Dellva, M., Coutant, D., LaBell, E., Reddy, S., Bowerman, S., Heise, T., Andersen, G., Zijlstra, E., Hermanski, L., Nosek, L., Linnebjerg, H.
Ultra rapid lispro (URLi) accelerates insulin lispro absorption and insulin action vs lispro in patients with type 2 diabetes.
Diabetologia 62 (Suppl 1):A786, 2019

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Diabetes 68(Suppl. 1):1112-P, 2019.

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Dance 501 inhaled human insulin (INH): linear dose response, earlier onset of action, and higher early effect than s.c. insulin lispro (LIS).
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Diabetes 68(Suppl. 1):1010-P, 2019.
77. Herbrand, T., Coester, H.V., DeVries, J.H., Heiss, C., Heise, T., Kelm, M., Sansone R.
More precise assessment of flow-mediated dilation (FMD) by measuring at maximum dilatatory peak time (MDP) in subjects with and without type 2 diabetes (T2D).
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78. Kapitza, C., Nosek, L., Lehmann, A., Schmider, W., Rotthaeuser, B., Nowotny, I.K. Comparative PK and PD of the rapid-acting insulin aspart product SAR341402, NovoLog, and NovoRapid in subjects with T1D.
Diabetes 68(Suppl. 1):130-LB, 2019.

**55th Annual Conference of the German Diabetes Association (DDG). Berlin, Germany,
May 29 – June 1, 2019**

79. Kapitza, C., Leohr, J., Liu, R., Reddy, S., Dellva, M.A., Matzopoulos, M., Knadler, M.P., Loh, M.T., Hardy, T., Kazda, C., Manning, M.
Ultra rapid lispro (URLi) reduces postprandial glucose excursions vs. humalog® in patients with T2D at multiple meal-to-dose timing intervals
Diabetologie und Stoffwechsel 14(S 01):S45, 2019
80. Kazda, C., Leohr, J., Liu, R., Hardy, T., Reddy, S., Pih Chng Chua, S., Guo, X., Hövelmann, U., Kapitza, C., Schloot N.
Ultra rapid lispro (URLi) shows faster insulin absorption vs. lispro during insulin pump (CSII) use in patients with T1D
Diabetologie und Stoffwechsel 14(S 01):S89-S90, 2019
81. Plum-Mörschel, L., Leohr, J., Liu, R., Reddy, S., Dellva, M.A., Lim, S., Loh, M.T., Knadler, M.P., Hardy, T., Kazda, C., Schloot, N.
Ultra rapid lispro (URLi) reduces postprandial glucose excursions vs. humalog® in patients with T1D at multiple meal-to-dose timing intervals
Diabetologie und Stoffwechsel 14(S 01):S90, 2019
82. Suico, J., Hövelmann, U., Zhang, S., Shen, T., Bergman, B., Sherr, J., Zijlstra, E., Frier, B., Plum-Mörschel, L., Mönnig E.
Nasal glucagon: a viable alternative to treat insulin-induced hypoglycaemia in adults with type 1 diabetes
Diabetologie und Stoffwechsel 14(S 01):S38, 2019

**12th International Conference on Advanced Technologies and Treatments for Diabetes (ATTD).
Berlin, Germany - February 20 – 23, 2019**

83. Ranson, A., Hövelmann, U., Seroussi, C., Lamers, D., Correia, J., Zijlstra, E., Meiffren G., Gaudier M., Soula A., Duracher D.
Biochaperone glucagon, a stable ready-to-use liquid glucagon formulation enabled by biochaperone technology, is well tolerated and quickly restores euglycemia after insulin-induced hypoglycemia
Diabetes Technol. Ther. 21 (S1):A-43, 2019
84. Hövelmann, U., Brændholt, O.M., Mouritzen, U., Lamers, D., Kronshage, B., Heise, T.
Small doses of dasiglucagon consistently increase plasma glucose (Pg) levels from hypoglycemia and euglycemia in people with type 1 diabetes mellitus (T1DM).
Diabetes Technol. Ther. 21 (S1):A-36, 2019

85. Mégret, C., Meiffren, G., Plum-Mörschel, L., Herbrand, T., Klein, O., Anastassiadis, E., Gaudier, M., Soula, O., Alluis, B., Heise, T.
Biochaperone combo, a co-formulation of lispro and glargine, improves postprandial glucose control compared to Lispromix25 or lispro and glargine injections in type 2 diabetes subjects.
Diabetes Technol. Ther. 21(S1):A-130, 2019
86. Suico, J., Hövelmann, U., Zhang, S., Shen, T., Bergman, B., Sherr, J., Zijlstra, E., Frier, B., Plum-Mörschel, L.
Nasal glucagon: a viable alternative to treat insulin-induced hypoglycemia in adults with type 1 diabetes
Diabetes Technol. Ther. 21(S1):A-33, 2019

Advanced training courses



Science Circle

87. Dr. Eric Zijlstra
Profil GmbH, Neuss, Germany
Nasal glucagon.
April 9, 2019
88. Dr. Daniela Lamers
Profil GmbH, Neuss, Germany
BioChaperone Glucagon.
April 9, 2019
89. Ulrike Hövelmann
Profil GmbH, Neuss, Germany
Dasiglucagon.
April 9, 2019
90. Prof. Dr. Hans de Vries
Profil GmbH, Neuss, Germany
Glucagon for the treatment of hypoglycemia and its use in artificial pancreas systems.
April 9, 2019

91. Annelie Fischer
Profil GmbH, Neuss, Germany
Statistical considerations in bioequivalence studies.
October 8, 2019
92. Dr. Susanne Famulla
Profil GmbH, Neuss, Germany
Bioequivalence study I.
October 8, 2019
93. Oliver Klein
Profil GmbH, Neuss, Germany
Bioequivalence study II.
October 8, 2019
94. Dr. Tim Heise
Profil GmbH, Neuss, Germany
Current status and the future of insulin bioequivalence studies.
October 8, 2019

Training Clinical Trial Recruitment Team

95. Dr. Sabine Arnolds
Profil GmbH, Neuss, Germany
Update CSII / CGM / closed loop systems.
November 25, 2019
96. Dr. Sabine Arnolds
Profil GmbH, Neuss, Germany
Diabetic nephropathy.
July 8, 2019
97. Dr. Sabine Arnolds
Profil GmbH, Neuss, Germany
New insulins.
May 13, 2019
98. Dr. Sabine Arnolds
Profil GmbH, Neuss, Germany
Management of type 2 diabetes.
February 18, 2019

External training course

99. Dr. Sabine Arnolds
Profil GmbH, Neuss, Germany
Profil – Glucose clamps – ClampArt.
Diabetes research training for a sponsor's North Rhine-Westphalia management team.
September 9, 2019

Profil Mainz Open House Day

100. Dr. Marcel Ermer
Profil Mainz GmbH & Co. KG, Mainz, Germany
Clinical study: from planning to implementation.
June 29, 2019
101. PD Dr. Leona Plum – Mörschel, Stephan Ganz
Profil Mainz GmbH & Co. KG, Mainz, Germany
Diabetes and new research approaches.
June 29, 2019
102. Lea Berk
Profil GmbH, Neuss, Germany
Nutrition and diabetes.
June 29, 2019

Trainings Clinical Pharmacology



103. Dr. Sybille Dellweg
Profil GmbH, Neuss, Germany
NIS – Non interventional studies.
November 7, 2019

104. Dr. Petra Schwaiger
Profil Mainz GmbH & Co. KG, Mainz, Germany
Cardiovascular diseases.
October 24, 2019
105. Dr. Marc Stoffel
Profil GmbH, Neuss, Germany
Start dose and escalation in FIH Studies.
October 10, 2019
106. Dr. Grit Andersen
Profil GmbH, Neuss, Germany
Preclinical documentation and Investigator Brochure.
September, 9 2019
107. Dr. Mirjam Ehren
Profil Mainz GmbH & Co. KG, Mainz, Germany
Intoxication.
August 22, 2019
108. Dr. Mirjam Ehren
Profil Mainz GmbH & Co. KG, Mainz, Germany
Detection and treatment of acute emergencies.
July 25, 2019
109. Nicole Vos-Schmitz
Profil GmbH, Neuss, Germany
Quality management in clinical research.
July 8, 2019
110. Dr. Klaus Peter Thiele
Profil GmbH, Neuss, Germany
Health economics.
June 18, 2019
111. Gary Scheiner
Owner, Clinical Director – Integrated Diabetes Services, Wynnewood, USA
Experience with pramlintide. May
27, 2019
112. Dr. Verena Schädlich
Profil Mainz GmbH & Co. KG, Mainz, Germany
Pharmacotherapy of pain.
May 21, 2019

113. Ernestos Anastassiadis
Profil GmbH & Co. KG, Mainz, Germany
Interdisciplinary cooperation.
April 25, 2019
114. Dr. Klaus Peter Thiele
Profil GmbH, Neuss, Germany
Healthcare structures.
February 18, 2019
115. Dr. Grit Andersen
Profil GmbH, Neuss, Germany
Pharmacoepidemiology.
January 15, 2019

Granted Research Consortia

116. EIT Health e.V. and EIT Health Germany GmbH



A Knowledge and Innovation Community (KIC) on Healthy Living and Active Ageing, funded by the European Institute of Innovation and Technology (EIT).
First funding period: 2015 – 2022
<http://eithealth.eu/>

Profil GmbH is EIT Health core partner and a full voting member of the EIT Health e.V. Partner Assembly.

Profil GmbH is represented in the EIT Health Germany GmbH Supervisory Board.

EIT Health innovation project

CLOSE: Automated Glucose Control at Home for People with Chronic Disease.



Members of the CLOUSE Consortium & guests. Barcelona, September, 2019.

Funding period: July 2016 – December 2019

Involved EIT Health partners: Air Liquide Healthcare, Sanofi, Profil GmbH, Profil Mainz GmbH & Co. KG, IESE Business School, Catholic University Leuven, Medical University of Lodz.

Additional project partners: Aqua Institute for Applied Quality Improvement and Research in Health Care, European Research and Project Office GmbH

Coordinating organisation: Profil GmbH

<https://eithealth.eu/project/close/>

<https://eit-health.de/en/close/>

<https://journals.sagepub.com/doi/full/10.1177/1932296818803588>



Members of the D4Teens Consortium. Paris, July 2019.

EIT Health innovation project :

D4Teens: Diabeloop for Teens.

Funding period: January 2019 – December 2020

Involved EIT Health partners: Commissariat à l'énergie atomique et aux énergies alternatives - laboratoire d'électronique des technologies de l'information (CEA-Leti), Profil GmbH, Katholic University Leuven, Karolinska Institutet, RISE – Research Institutes of Sweden, Ceritd.

Additional partner: Diabeloop.

Coordinating organisation: CEA-Leti

<https://eithealth.eu/project/d4teens/>

EIT Health innovation project :

iPDM-GO: Integrated Personalized Diabetes Management (iPDM) Goes Europe.

Funding period: January 2019 – December 2021

Involved EIT Health partners: Roche Diabetes Care, Profil Neuss, German Center for Diabetes Research, University of Copenhagen, Danmarks Tekniske Universitet, Helmholtz Center Munich, City of Copenhagen, Capital Region of Denmark

Additional partner: LINQ management

Coordinating organisation: Roche Diabetes Care

<https://eithealth.eu/project/ipdm-go/>

<https://eit-health.de/en/ipdm-go/>

117. Competence Center for Biomarker Research in Medicine (CBMED).

COMET K1 Center for Biomarker Research at CBmed.

Funded by the Austrian Research Promotion Agency

First funding period: 2015 – 2019

<https://www.cbmed.at/>

Profil Neuss is chairing the consortium board of the CBmed GmbH.

Scientific Communication

Webinars



 **profil**
ANSWERS FOR DIABETES

Presented by:
Dr. Tim Heise
Lead Scientist - Chairman of the Board
of Directors at Profil



Register for the free webinar:
“Understanding the results of glucose clamp studies“

<http://www.profil.com/knowledge-center/webinars>

118. **Understanding the results of glucose clamp studies.**
T. Heise. March 5, 2019
119. **Diagnosis of nonalcoholic fatty liver disease (NAFLD) – performance characteristics of available diagnostic procedures.**
Prof. Dr. A. Erhardt. May 8, 2019



Blogs

<http://blog.profil.com/blog>

120. **Beer or wine or both – and if both, in which order?**
D. Lamers. December 10, 2019
121. **Profil World - The clinical diabetes research newsletter - November 2019.**
S. Meister. November 26, 2019
122. **Lipohypertrophy – New insights into an old issue?**
S. Famulla. November 14, 2019
123. **What news in the treatment of Type 2 diabetes was presented at EASD 2019?**
J. Arrubla. October 17, 2019
124. **Finally breakthrough in the immunological approach to type 1 diabetes.**
H. DeVries. October 1, 2019
125. **Current developments in approaches to bridging studies.**
G. Andersen September 17, 2019
126. **iPDM goes Europe: tangible impact on diabetes patients and care.**
F. Schliess. September 3, 2019
127. **New PID-algorithm for automated glucose clamps.**
C. Benesch. August 21, 2019
128. **"Profil World" - The clinical diabetes research newsletter – July 2019.**
S. Meister. July 23, 2019
129. **Dual-hormone artificial pancreas systems.**
U. Hövelmann. July 16, 2019
130. **Dr. Tim Heise about Profil's 2018 Science Report.**
T. Heise. July 2, 2019
131. **Is there a 'true' insulin time action profile?**
O. Klein. June 18, 2019
132. **Applications of iontophoresis in studies investigating microvasculature.**
J. Arrubla. June 4, 2019

133. **The ideal basal insulin?**
E. Zijlstra. May 21, 2019
134. **"Profil World" - The clinical diabetes research newsletter - May 2019.**
S. Meister. May 6, 2019
135. **Profil is co-founder of KomIT.**
S. Meister. April 30, 2019
136. **NAFLD/NASH: a ticking bomb not yet defused.**
F. Schliess. April 25, 2019
137. **Profil joined iPDM-GO.**
F. Schliess. April 16, 2019
138. **Free webinar on diagnosis of NAFLD.**
S. Meister. April 9, 2019
139. **Are soccer players with dark skin tone more likely to receive red cards?**
H. DeVries. March 12, 2019
140. **"Profil World" - The clinical diabetes research newsletter - February 2019.**
S. Meister. February 27, 2019
141. **Artificial pancreas in type 2 diabetes.**
F. Schliess. February 19, 2019
142. **Free webinar titled "Understanding the results of glucose clamp studies".**
S. Meister. February 5, 2019
143. **Digital Diabetes: better trials, better drugs, better care.**
F. Schliess. January 29, 2019
144. **Glucose-Infusion-Rate based categorization of glucose clamps.**
M. Kuhlenkötter. January 15, 2019
145. **Update on Brexit: impact on future and current clinical trials in Germany.**
G. Andersen. January 8, 2019

Media Reports (Selection)

146. Bremer, A.W. & Arreaza-Rubin, G.
Analysis of “Artificial Pancreas (AP) systems for people with type 2 diabetes: conception and design of the European CLOSE project”.
J. Diabetes Sci. Res. 13(2):268-270, 2019
147. **EIT Health’s CLOSE project recognized by researchers from the National Institutes of Health (NIH).**
EIT Health News, August 22, 2019
148. **Freimut Schliess Blog Post: Digital Diabetes and EIT Health.**
EIT Health News, August 22, 2019
149. **Profil Institut für Stoffwechselforschung GmbH**
Center of Competence for Innovative Diabetes Therapy, 2019

