Science Report 2021

www.profil.com

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

Preface: What Science Can Do

“What science can do” was the title of an address president Barack Obama gave at the annual meeting of the National Academy of Sciences on April 28, 2009 (published in Issues in Science and Technology 25, no. 4). His speech contained some remarkable thoughts that seem to be even more relevant today. One of Barack Obama’s most prominent statements was that “science is more essential for our prosperity, our security, our health, our environment, and our quality of life than it has ever been before”.

This seems to be obvious in the times of a global pandemic. The unprecedentedly fast discovery and development of efficacious vaccines literally saved millions of lives. But despite these impressive scientifc achievements, there are still hundreds and thousands of people dying from COVID-infections all around the globe every day. In developed countries such as Germany, most deaths occur in people that refused to get vaccinated despite all the clear evidence for the vaccine’s efficacy to prevent serious complications. In fact, the public trust in science and research has been notoriously low in Germany with less than 50% of the general population expressing trust in science and research in 2019 (Bromme R, et al. PLoS ONE 2022; 17: e0262823). While this number rose to 73% during the pandemic, this still means that more than a quarter of the population does not have confidence in science – in times where the value of science is more obvious than ever.

This would imply that science can only do what most people accept. But there might also be a

different view on the value of science, and that is the viewpoint of patients, in particular patients suffering from chronic diseases like diabetes. They appreciate any scientific improvement that helps to ease their daily life as can be seen by the rapid pick-up of continuous glucose monitoring and closed loop devices whose performance has so much improved in the last years.

At Profil, we are proud of our contribution to the progress in diabetes therapy, as small as it might be. Vigorously testing new therapies and devices in clinical studies performed at highest quality standards and at ambitious timelines is our passion, and the positive feedback we get from our study participants with diabetes is a perseverative motivation to further improve our research and thereby eventually diabetes therapy. But even the best clinical study would be imperfect without being published. Barack Obama rightly pointed out that “so many of the challenges that science and technology will help us meet are global in character” – diabetes and obesity are a good example. So we “need to work with our friends around the world” – and this is only possible when sharing our findings through publications. The 29 publications with contributions of Profil scientists in 2021 covered a lot of different areas (e.g. incretins, glucagon, different insulins and combinations of insulin with other agents, continuous glucose monitoring, to only name a few). The interest of the scientific community in this research is best reflected at an impressive cumulative impact factor of > 245 – another motivation to carry on and improve! My sincere thanks go out to all the people that contributed to this success, from our scientists over the whole clinical staff to sponsors, collaborators and study participants who confide in our expertise and confidence.

I would like to conclude with another statement from President Obama’s address: “Science cannot supplant our ethics or our values, our principles or our faith. But science can inform those things and help put those values—these moral sentiments, that faith—can put those things to work—to feed a child or to heal the sick, to be good stewards of this Earth.” Indeed, this is what science can do – and at Profil, we will continue our small contribution to scientific improvements in 2022 and beyond.

Content

Metrics

TABLE 1: TOTAL OUTPUT			
	Count	Σ Impact Factors	Mean Impact Factor
Scientific Publications	**29**	**249,56**	**9,60**
Original Articles	16	140,46	9,36
Reviews	6	59,71	9,95
Books/Letters/Comment	7	47,53	11,88
Scientific Congress Presentations	**36**	n/a	n/a
Orals	27	n/a	n/a
Poster	9	n/a	n/a
Advanced Trainings	**9**	n/a	n/a
Granted Research Consortia	**4**	n/a	n/a
Scientific Communication	**26+**	n/a	n/a
Online Seminars	4	n/a	n/a
Blog Posts	14	n/a	n/a
Media Appearance	8+	n/a	n/a

TABLE 2: PROFIL SCIENTIST(S) FIRST/SENIOR AUTHOR	Count	Σ Impact Factors	Mean Impact Factor
Scientific Publications	**12**	**65,49**	**7,28**
Original Articles	8	59,89	7,49
Reviews	1	5,60	5,60
Books/Letters/Comment	3	0,00	0,00
Scientific Congress Presentations	**27**	n/a	n/a
Orals	21	n/a	n/a
Poster	6	n/a	n/a

TABLE 3: PUBLISHED STUDIES (PARTLY) OPERATED BY PROFIL	Count	Σ Impact Factors	Mean Impact Factor
Scientific Publications	**13**	**111,88**	**8,61**
Original Articles	13	111,88	**8,61**
Reviews	n/a	n/a	n/a
Letters/Comments	n/a	n/a	n/a
Scientific Congress Presentations	**29**	n/a	n/a
Orals	20	n/a	n/a
Poster	9	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	**8**	**59,89**	**7,49**
Original Articles	8	59,89	7,49
Reviews	n/a	n/a	n/a
Letters/Comments	n/a	n/a	n/a
Scientific Congress Presentations	**21**	n/a	n/a
Orals	15	n/a	n/a
Poster	6	n/a	n/a

Scientific Publications

Original Articles

1. Bianzano, S., Heise, T., Jungnik, A., Schepers, C., Schölch, C., Gräfe-Mody, U.
Safety, tolerability, pharmacokinetics and pharmacodynamics of single oral doses of BI 187004, an inhibitor of 11beta-hydroxysteroid dehydrogenase-1, in healthy male volunteers with overweight or obesity.
Clin. Diabetes Endocrinol. 7(1):16
IF(2022): 1.858

2. Flint, A., Andersen, G., Hockings, P., Johansson, L., Morsing, A., Sundby Palle, M., Loomba, R., Vogl, T.J., Plum-Mörschel, L.
Randomized clinical trial: Semaglutide versus placebo reduced liver steatosis but not liver stiffness in subjects with non-alcoholic fatty liver disease assessed by magnetic resonance imaging.
Aliment. Pharmacol. Ther. 54(9):1150-1161, 2021
IF(2021): 8.171

3. Leohr, J., Kazda, C., Liu, R., Reddy, S., Dellva, M.A., Matzopoulos, M., Loh, M.T., Hardy, T., Klein, O., Kapitza, C.
Ultra rapid lispro (URLi) shows faster pharmacokinetics and reduces postprandial glucose excursions versus Humalog® in patients with type 2 diabetes mellitus in a randomized, controlled crossover meal test early-phase study.
Diabetes Obes. Metab. 2021 Oct 04. doi:10.1111/dom.14561
IF(2021): 6.577

4. Kazda, C., Leohr, J., Liu, R., Reddy, S., Dellva, M.A., Loh, M.T., Hardy, T., Plum-Mörschel, L.
Ultra rapid lispro (URLi) shows accelerated pharmacokinetics and greater reduction in postprandial glucose versus Humalog® in patients with type 1 diabetes mellitus in a randomized, double-blind meal test early-phase study.
Diabetes Obes. Metab. 2021 Sep 30. doi:10.1111/dom.14563. Online ahead of print.
IF(2021): 6.577

5. Hövelmann, U., Raiter, Y., Chullikana, A., Liu, M., Donnelly, C., Lawrence, T., Sengupta, N., Cl, G., Ranganna, G., Barve, A.
Pharmacokinetic and pharmacodynamic bioequivalence of biosimilar MYL-1601D with US and European insulin aspart in healthy volunteers: A randomized, double-blind, crossover, euglycaemic glucose clamp study.
Diabetes Obes. Metab. 23(12):2670-2678, 2021
IF(2021): 6.577

6. Quast, D.R., Nauck, M.A., Schenker, N., Menge, B.A., Kapitza, C., Meier, J.J.
Macronutrient intake, appetite, food preferences and exocrine pancreas function after treatment with short- and long-acting GLP-1 receptor agonists in type 2 diabetes.
Diabetes Obes. Metab. 23(10):2344-2353, 2021
IF(2021): 6.577

7. Herbrand, T., Coester, H.V., Sansone, R., Fischer, A., Heiss, C., Heise, T., Kelm, M. DeVries, J.H.
Improving the assessment of flow-mediated dilation through detection of peak time in healthy subjects and subjects with type 2 diabetes.
Angiology 72(5):434-441, 2021
IF(2021): 3.619

8. Bergougnan, L., Andersen, G., Plum-Mörschel, L., Evaristi, M.F., Poirier, B., Tardat, A., Ermer, M., Herbrand, T., Arrubla, J., Coester, H.V., Sansone, R., Heiss, C., Vitse, O., Hurbin, F., Boiron, R., Benain, X., Radzik, D., Janiak, P., Muslin, A.J., Hovsepian, L., Kirkesseli, S., Deutsch, P., Parkar, A.A.
Endothelial-protective effects of a G-protein-biased sphingosine-1 phosphate receptor-1 agonist, SAR247799, in type-2 diabetes rats and a randomized placebo-controlled patient trial.
Br. J. Clin. Pharmacol. 87(5):2303–2320, 2021
IF(2021): 4.335

9. Pieber, T.R., Aronson, R., Hövelmann, U., Willard, J., Plum-Mörschel, L., Knudsen, K.M., Bandak, B., Tehranchi, R.
Dasiglucagon: A next-generation glucagon analog for rapid and effective treatment of severe hypoglycemia results of phase 3 randomized double-blind clinical trial.
Diabetes Care 44(6):1361-1367, 2021
IF(2021): 19.112

10. Andersen, G., Meiffren, G., Famulla, S., Heise, T., Ranson, A., Seroussi, C., Eloy, R., Gaudier, M., Charvet, R., Chan, Y.P., Soula, O., DeVries, J.H.
ADO09, a co-formulation of the amylin analogue pramlintide and the insulin analogue A21G, lowers postprandial blood glucose versus insulin lispro in type 1 diabetes.
Diabetes Obes. Metab. 23(4):961–970, 2021
IF(2021): 6.577

11. Kapitza, C., Nosek, L., Schmider, W., Teichert, L., Mukherjee, B., Nowotny, I.
A single-dose euglycaemic clamp study in two cohorts to compare the exposure of SAR341402 (insulin aspart) Mix 70/30 with US- and European-approved versions of insulin aspart Mix 70/30 and SAR341402 rapid-acting solution in subjects with type 1 diabetes.
Diabetes Obes. Metab. 23(3):674-681, 2021
IF(2021): 6.577

12. Benesch, C., Kuhlenkötter, M., Nosek, L., Heise, T.
New clamp-PID algorithm for automated glucose clamps improves clamp quality.
J. Diabetes Sci. Technol. 16(2):408-414, 2021
IF(2021): 2.677

13. Olafsdottir, A.F., Bolinder, J., Heise, T., Polonsky, W., Ekelund, M., Wijkman, M., Pivodic, A., Ahlén, E., Schwarcz, E., Nyström, T., Hellman, J., Hirsch, I.B., Lind, M.
The majority of people with type 1 diabetes and multiple daily insulin injections benefit from using continuous glucose monitoring: An analysis based on the GOLD randomized trial (GOLD-5).
Diabetes Obes. Metab. 23(2):619-630, 2021
IF(2021): 6.577

14. Huang, J., Covic, M., Huth, C., Rommel, M., Adam, J., Zukunft, S., Prehn, C., Wang, L., Nano, J., Scheerer, M.F., Neschen, S., Kastenmüller, G., Gieger, C., Laxy, M., Schliess, F., Adamski, J., Suhre, K., de Angelis, M.H., Peters, A., Wang-Sattler, R.
Validation of candidate phospholipid biomarkers of chronic kidney disease in hyperglycemic Individuals and their organ-specific exploration in leptin receptor-deficient db/db mouse.
Metabolites 3;11(2):89, 2021
IF(2021): 4.754

15. Eckstein, M.L., Farinha, J.B., McCarthy, O., West, D.J., Yardley, J.E., Bally, L., Zueger, T., Stettler, C., Boff, W., Reischak-Oliveira, A., Riddell, M.C., Zaharieva, D.P., Pieber, T.R., Müller, A., Birnbaumer, P., Aziz, F., Brugnara, L., Haahr, H., Zijlstra, E., Heise, T., Sourij, H., Roden, M., Hofmann, P., Bracken, R.M., Pesta, D., Moser, O.
Differences in physiological responses to cardiopulmonary exercise testing in adults with and without type 1 diabetes: A pooled analysis.
Diabetes Care 44:240-247, 2021
IF(2021): 19.112

16. Lind, M., Ólafsdóttir, A.F., Hirsch, I.B., Bolinder, J., Dahlqvist, S., Pivodic, A., Hellman, J., Wijkman, M., Schwarcz, E., Albrektsson, H., Heise, T., Polonsky, W.
Sustained intensive treatment and long-term effects on HbA1c reduction (SILVER Study) by CGM in people with type 1 diabetes treated with MDI.
Diabetes Care 44:141-149, 2021
IF(2021): 19.112

Reviews

17. Heise, T.
The future of insulin therapy.
Diabetes Res. Clin. Pract. 175:108820, 2021
IF(2021): 5.602

18. Shang, T., Zhang, J.Y., Bequette, B.W., Raymond, J.K., Coté, G., Sherr, J.L., Castle, J., Pickup, J., Pavlovic, Y., Espinoza, J., Messer, L.H., Heise, T., Mendez, C.E., Kim, S., Ginsberg, B.H., Masharani, U., Galindo, R.J., Klonoff, D.C.
Diabetes Technology Meeting 2020
J. Diabetes Sci. Technol. 15(4):916-960
IF(2021): 2.677

19. Jones, A., Bardram, J.E., Bækgaard, P., Cramer-Petersen, C.L., Skinner, T., Vrangbæk, K., Starr, L., Nørgaard, K., Lind, N., Bechmann Christensen, M., Glümer, C., Wang-Sattler, R., Laxy, M., Brander, E., Heinemann L., Heise T., Schliess F., Ladewig, K., Kownatka, D.
Integrated personalized diabetes management goes Europe: A multi-disciplinary approach to innovating type 2 diabetes care in Europe.
Prim. Care Diabetes 15(2):360-364, 2021
IF(2021): 2.459

20. Hulst, A.H., Polderman, J.A.W., Siegelaar, S.E., van Raalte, D.H., DeVries, J.H., Preckel, B., Hermanides, J.
Preoperative considerations of new long-acting glucagon-like peptide-1 receptor agonists in diabetes mellitus.
Br. J. Anaesth. 126(3):567-571, 2021
IF(2021): 9.166

21. Steenblock,C., Schwarz, P.E.H., Ludwig, B., Linkermann, A., Zimmet, P., Kulebyakin, K., Tkachuk, V.A., Markov, A.G., Lehnert, H., de Angelis, M.H., Rietzsch, H., Rodionov, R.N., Khunti, K., Hopkins, D., Birkenfeld, A.L., Boehm, B., Holt, R.I.G., Skyler, J.S., DeVries, J.H., Renard, E., Eckel, R.H., Alberti, K.G.M.M., Geloneze, B., Chan, J.C., Mbanya, J.C., Onyegbutulem, H.C., Ramachandran, A., Basit, A., Hassanein, M., Bewick, G., Spinas, G.A., Beuschlein, F., Landgraf, R., Rubino, F., Mingrone, G., Bornstein, S.R.
COVID-19 and metabolic disease: mechanisms and clinical management.
Lancet Diabetes Endocrinol. 9(11):786-798, 2021
IF(2021): 32.069

22. Bornstein S.R., Rubino F., Ludwig B., Rietzsch H., Schwarz P.E.H, Rodionov R.N., Khunti K., Hopkins D., Birkenfeld A.L., Boehm B., Amiel S., Holt R.I.G, Skyler J.S., DeVries J.H., Renard E., Eckel R.H., Zimmet P., Alberti K.G., Geloneze B., Chan J.C., Mbanya J.C., Onyegbutulem H.C., Ramachandran A., Basit A., Hassanein M., Spinas G.A., Beuschlein F., Mingrone G.
Consequences of the COVID-19 pandemic for patients with metabolic diseases.
Nat. Metab. 3(3):289-292, 2021
IF(2021): 7.740

Books/Letters/Comments

23. Holt, R.I.G., DeVries, J.H., Hess-Fischl, A., Hirsch, I.B., Kirkman, M.S., Klupa, T., Ludwig, B., Nørgaard, K., Pettus, J., Renard, E., Skyler, J.S., Snoek, F.J., Weinstock, R.S., Peters, A.L.
The management of type 1 diabetes in adults. A consensus report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD).
Diabetologia 64(12):2609-2652, 2021
IF(2021): 10.122

24. Holt, R.I.G., DeVries, J.H., Hess-Fischl, A., Hirsch, I.B., Kirkman, M.S., Klupa, T., Ludwig, B., Nørgaard, K., Pettus, J., Renard, E., Skyler, J.S., Snoek, F.J., Weinstock, R.S., Peters, A.L.
The management of type 1 diabetes in adults. A consensus report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD).
Diabetes Care 44(11):2589-2625, 2021
IF(2021): 19.112

25. Flint, A., Andersen, G., Hockings, P., Plum-Mörschel, L., Loomba, R.
Editorial: Evolution of GLP-1 receptor agonists as pharmacotherapy for NASH beyond diabetes mellitus and obesity – authors' reply.
Aliment. Pharmacol. Ther. 54(11-12):1498, 2021
IF(2021): 8.171

26. Moser, O., Riddell, M.C., Eckstein, M.L., Adolfsson, P., Rabasa-Lhoret, R., van den Boom, L., Gillard, P., Nørgaard, K., Oliver, N.S., Zaharieva, D.P., Battelino, T., de Beaufort, C., Bergenstal, R.M., Buckingham, B., Cengiz, E., Deeb, A., Heise T., Heller, S., Kowalski, A.J., Leelarathna, L., Mathieu, C., Stettler, C., Tauschmann, M., Thabit, H., Wilmot, E.G., Sourij, H., Smart, C.E., Jacobs, P.G., Bracken, R.M., Mader, J.K.
Glucose management for exercise using continuous glucose monitoring: should sex and prandial state be additional considerations? Reply to Yardley JE and Sigal RJ [letter].
Diabetologia 64(4):935–938, 2021
IF(2021):10.122

27. Schliess, F.
Proving the effectiveness of digital health technologies,
Open Access Government ISSN 2516-3817
October 6, 2021
IF: -

28. Schliess, F.
What does the European Medical Devices Regulation 2017/745 (MDR) say about clinical trials?
Open Access Government ISSN 2516-3817
June 21, 2021
IF: -

29. Schliess, F.
On the fast-track to reimbursement: Germany unlocks business opportunities for digital health innovators.
Open Access Government
Special Health and Social Care Report
January 10, 2021
IF: -

Scientific Presentations

Oral Presentations

RealWorld4Clinic EIT Health ELSI Board workshop (Part 2). Virtual, December 8, 2021

30. Rüling, C.-C., Reineke, J.-P., Schliess, F.
AI-powered health monitoring for clinical research

***3*rd European Digital Week. Frankfurt/Main, Germany, November 1–5, 2021.**

31. Schliess, F.
Moderation of the 2nd Frankfurt AI Forum Session “AI and healthcare”.

Join Health (Health Cluster Portugal, EIT Health InnoStars). Virtual, November 2, 2021

32. Schliess, F.
Remote decentralized clinical trials: Towards more sustainability, resilience & external validity in pivotal clinical research?

XXIII Congresso Nazionale Associazione Medici Diabetologi (AMD). Bologna, Italy, October 27–30, 2021

33. Leohr, J., LaBell, E., Dellva, M.A., Tong, Z., Arrubla, J., Plum-Mörschel, L., Zijlstra, E., Fukuda, T., Hardy, T.
Faster recovery from hyperglycemia with ultra rapid lispro (URLi) vs Humalog® in patients with type 1 diabetes (T1D) on continuous subcutaneous insulin infusion (CSII).

Joint EIT Health Germany and EIT Health Scandinavia Symposium. Mannheim, Germany, October 19–20, 2021

34. Schliess, F.
Remote decentralized clinical trials: Towards more sustainability, resilience & external validity in pivotal clinical research?

62nd National Congress of the Spanish Society of Endocrinology and Nutrition. Seville, Spain, October 13–15, 2021

35. Leohr, J., LaBell, E., Dellva, M.A., Tong, Z., Arrubla, J., Plum-Mörschel, L., Zijlstra, E., Fukuda, T., Hardy, T.
Faster recovery from hyperglycemia with ultra rapid lispro (URLi) vs Humalog® in patients with type 1 diabetes (T1D) on continuous subcutaneous insulin infusion (CSII).

EIT Health Germany: Start-ups meet healthcare provider. Virtual, October 13, 2021

36. Schliess, F.
Clinical trialing digital health technologies.

9th DZD Diabetes Research School "Healthcare research – integrated personalised diabetes management". Virtual, October 7–14, 2021

37. Schliess, F.
Moderation of the satellite-event "iPDM-GO – a pan-European approach to science & innovation in diabetes care.

38. Heinemann, L.
Structured feedback loops in diabetes care: from the conception to the proof-of-concept of an integrated personalised diabetes management (iPDM).

39. Schliess, F.
iPDM Goes Europe (iPDM-GO): A pan-European collaboration initiative for implementation of iPDM in value-based healthcare.

57th European Association for the Study of Diabetes (EASD) Annual Meeting. Virtual, September 29 – October 1, 2021

40. Zijlstra, E., Heise, T., Ermer, M., Lu, J., Wilson, M., Plum-Mörschel, L.
Proposed biosimilar insulin lispro (GL-LIS) shows pharmacokinetic (PK) and pharmacodynamic (PD) bioequivalence versus US-licensed and EU-authorised insulin lispro (LIS).
Diabetologia 64(Suppl 1):SO35, 2021

41. Heise T., Plum-Mörschel L., Andersen G., Lu J, Wilson M., Zijlstra E.
Proposed biosimilar insulin glargine (GL-GLA) shows pharmacokinetic (PK) and pharmacodynamic (PD) bioequivalence to US-licenced and EU-authorised insulin glargine.
Diabetologia 64(Suppl 1):SO35, 2021

42. Plum-Mörschel, L., Uhrmacher, E., Zijlstra, E., Lu, J., Wilson, M., Barton, M., Heise T.
Proposed biosimilar insulin aspart (GL-ASP) shows pharmacokinetic (PK) and pharmacodynamic (PD) bioequivalence to US-licenced and EU-authorised insulin aspart.
Diabetologia 64(Suppl 1):SO35, 2021

43. Leohr, J., Dellva, M.A., LaBell, E., Arrubla, J., Plum-Mörschel, L., Zijlstra, E., Fukuda, T., Hardy, T.
Faster recovery from hyperglycemia with ultra rapid lispro vs lispro in patients with type 1 diabetes (T1D) on continuous subcutaneous insulin infusion (CSII).
Diabetologia 64(Suppl 1):SO34, 2021

44. Heller, S., Battelino, T., Bailey, T., Tehranchi, R., Klaff, L., Pieber, T., Hövelmann, U., Plum-Mörschel, L., Melgaard, A.E., Aronson, R., DiMeglio, L., Danne, T.
Integrated safety analysis of dasiglucagon for the treatment of severe hypoglycaemia.
Diabetologia 64(Suppl 1):SO42, 2021

45. Danne, T., Bailey, T., Tehranchi, R., Klaff, L.J., Pieber, T., Hövelmann, U., Plum-Mörschel, L., Melgaard, A.E., Aronson, R., DiMeglio, L.A., Battelino, T.
The next-generation glucagon analogue dasiglucagon consistently achieves rapid recovery from hypoglycaemia across subgroups.
Diabetologia 64(Suppl 1):SO42, 2021

46. Meiffren, G., Andersen, G., Eloy, R., Seroussi, C., Megrét, C., Famulla, S., Chan, Y.-P., Gaudier, M., Soula, O., DeVries, J.H., Heise, T.
Ado09, a co-formultation of pramlintide and insulin A21G improves post-prandial

glucose and body weight versus insulin aspart in type 1 diabetes.
Diabetologia 64(Suppl 1):OP23, 2021

16th Health Insurance Summit. Berlin, Germany, September 16, 2021.

47. Diehl, A., Geier, A.S., Janssen, B.I., Maier, P., Matthies, H., Müller, N., Zurth, M., Rosenstock, M., Schliess, F., Weigant, C., Neubacher, D., Ladewig, K., Lüttgen, M., Schanz, C., Weller, N.
Roundtable discussion: DiGAs – a model for Europe?

American Diabetes Association (ADA) 81th Scientific Sessions. Seattle, USA. June 25–29, 2021

48. Leohr, J., LaBell, E., Dellva, M.A., Tong, Z., Arrubla, J., Plum-Mörschel, L., Zijlstra E., Fukuda, T., Hardy, T.
Faster recovery from hyperglycemia with ultra rapid lispro (URLi) vs Humalog® in patients with type 1 Diabetes (T1D) on continuous subcutaneous insulin infusion (CSII).
Diabetes 70(Suppl1):190-OR, 2021

49. Meiffren, G., Andersen, G., Eloy, R., Mégret, C., Famulla, S., Seroussi, C., Chan, Y.P., Gaudier, M., Soula, O., DeVries, J.H., Heise, T.
ADO09, a coformulation of insulin A21G and pramlintide (Pram) improves blood glucose control and reduces body weight in subjects with T1D.
Diabetes 70(Suppl 1):197-OR, 2021

14th International Conference on Advanced Technologies and Treatments for Diabetes (ATTD). Virtual, June 2–5, 2021

50. Zijlstra E.
Oral Insulins
Diabetes Technol. Ther. 23 Suppl. 2):O108, 2021

51. Heise T.
Smart Insulins.
Diabetes Technol. & Ther. 23 (Suppl. 2):O107, 2021

52. Meiffren, G., Andersen, G., Eloy, R., Seroussi, C., Mégret, C., Famulla, S., Chan, Y.P., Gaudier, M., Soula, O., DeVries, J.H., Heise, T.
ADO09, a co-formulation of pramlintide and insulin A21G improves post-prandial glucose versus insulin aspart in type 1 diabetes.
Diabetes Technol. Ther. 23(Suppl. 2):O090, 2021

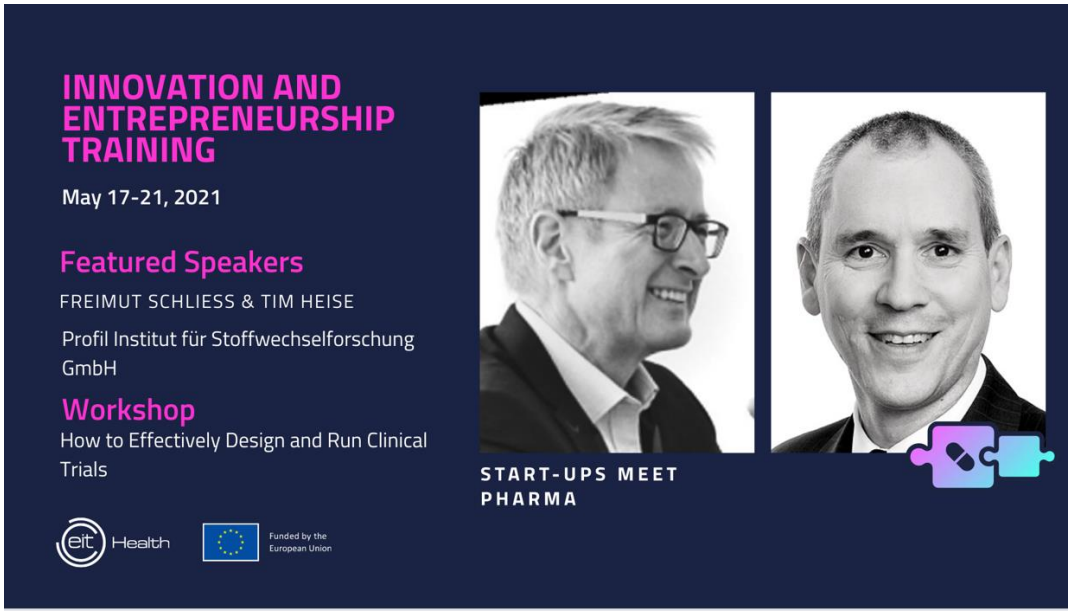
RealWorld4Clinic EIT Health ELSI Board workshop (Part 1). Virtual, May 20, 2021

53. Rüling, C.-C., Reineke, J.-P., Schliess, F.

AI-powered health monitoring for outpatient cardiology

EIT Health Germany Innovation and Entrepreneurship Training: Start-ups meet Pharma. Virtual, May 17 – 21, 2021

54. Schliess, F., Heise, T.
Workshop: How to effectively design and run clinical trials?



ENDO 2021 Annual Meeting of the Endocrine Society. Virtual. March 20–23, 2021

55. Heise, T., Chien, J., Beals, J., Benson, C., Klein, O., Moyers, J.S., Haupt, A., Pratt, E.J.
Basal insulin Fc (BIF), a novel insulin suited for once weekly dosing for the treatment of patients with diabetes mellitus.
JES 5(Suppl 1), A329, 2021

30th Annual Conference Asia Pacific for the Study of Liver (APASL). Virtual, February 4–6, 2021

56. Andersen, G.
New tools in diabetes therapy

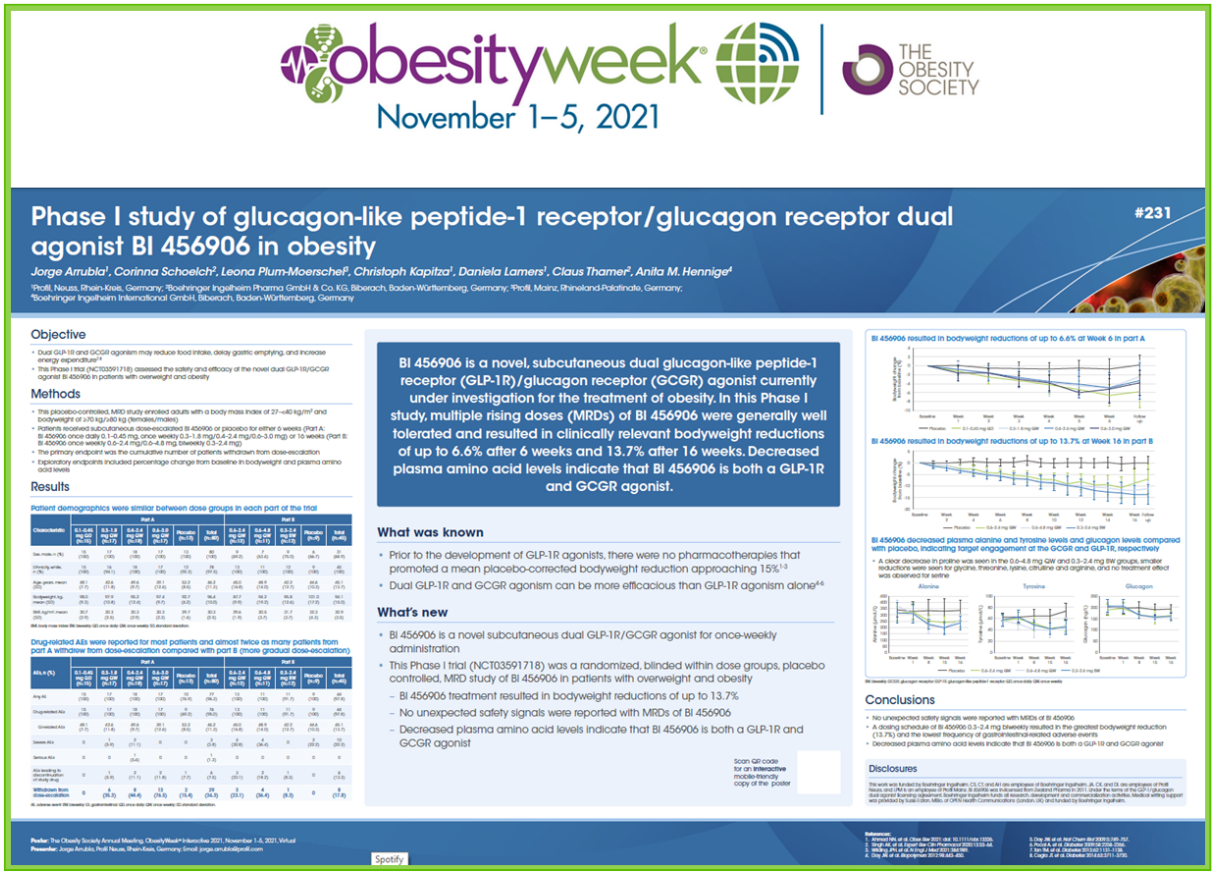
Poster Presentations

American Association for the Study of Liver Disease (AASLD) The Liver Meeting. Virtual, November 15–12, 2021

57. Flint, A., Andersen, G., Hockings, P., Johansson, L., Ersbøll, A., Sundby Palle, M.S., Vogl, T.J., Plum-Mörschel, L.
Semaglutide treatment in subjects with NAFLD: effects assessed by magnetic resonance elastography and magnetic resonance imaging proton density fat fraction.

Obesity Week 2021. Dallas, USA, November, 1–5, 2021

58. Arrubla, J. Schoelch, C., Plum-Mörschel, L., Kapitza, C., Lamers, D., Thamer C., Hennige A.
Phase I Study of glucagon-like peptide-1/glucagon receptor dual agonist BI456906 in obesity.



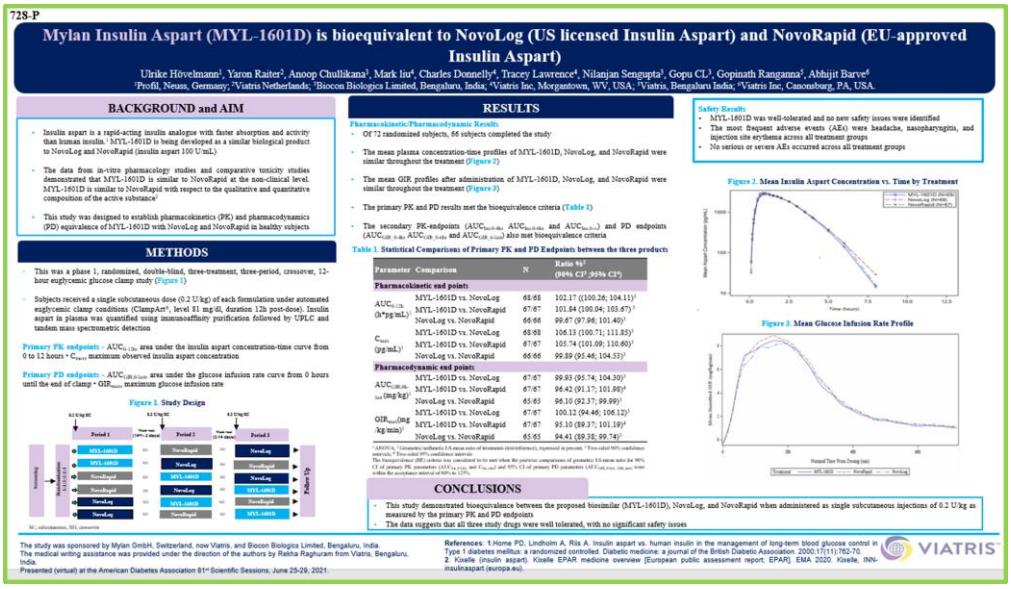
American Diabetes Association (ADA) 81th Scientific Sessions. Seattle, USA. June 25 – 29, 2021

59. Heise, T., Plum-Mörschel, L., Andersen, G., Lu, J., Wilson, M.G., Zijlstra, E.
Proposed biosimilar Gan & Lee insulin glargine (GL-GLA) shows pharmacokinetic (PK) and pharmacodynamic (PD) bioequivalence (BE) to US- and EU-licensed insulin glargine (IG).
Diabetes 70(Suppl 1):740-P, 2021

60. Plum-Mörschel, L., Uhrmacher, E., Zijlstra, E., Lu J., Wilson M.G., Barton M.E., Heise, T.
Proposed biosimilar Gan & Lee insulin aspart (GL-ASP) shows pharmacokinetic (PK) and pharmacodynamic (PD) bioequivalence (BE) to US- and EU-licensed insulin aspart (ASP).
Diabetes 70(Suppl 1):738-P, 2021

61. Zijlstra, E., Heise, T., Ermer, M., Lu, J., Wilson, M.G., Plum-Mörschel, L.
Proposed biosimilar Gan & Lee insulin lispro (GL-LIS) shows pharmacokinetic (PK) and pharmacodynamic (PD) bioequivalence (BE) versus US- and EU-licensed insulin lispro (LIS).
Diabetes70 (Suppl 1):736-P, 2021

Hövelmann, U., Raiter, Y., Chullikana, A., Liu, M., Donnelly, C., Lawrence, T., Sengupta, N., Cl, G., Ranganna, G., Barve, A.
Mylan insulin aspart (MYL-1601D) is bioequivalent to NovoLog (US licensed Insulin Aspart) and NovoRapid (EU-approved Insulin Aspart).
Diabetes 70(Suppl 1):728-P, 2021



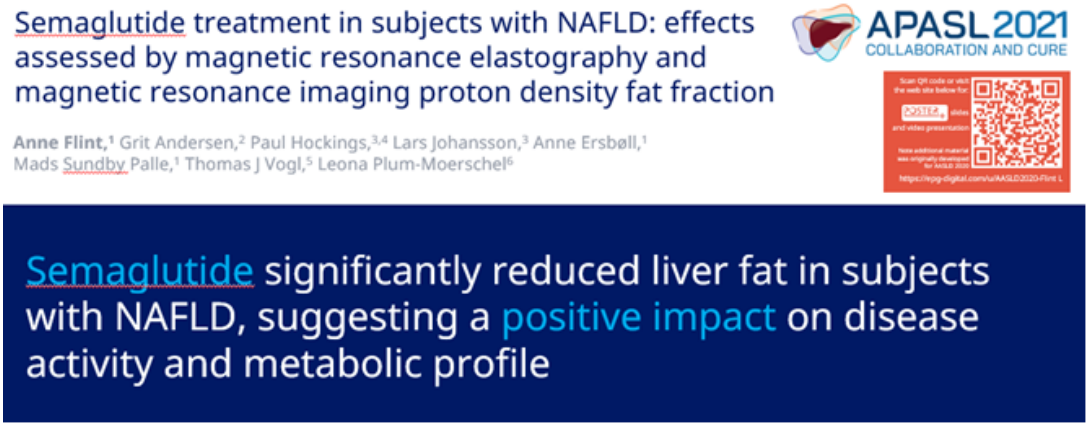
62. Battelino, T., Bailey, T., Tehranchi, R., Klaff, L.J., Pieber, T.R., Hövelmann, U., Plum-Mörschel, L., Melgaard, A.E., Aronson, R., DiMeglio, L.A., Danne, T., Peters, A.
Predicting true time to recovery from insulin-induced hypoglycemia with dasiglucagon.
Diabetes 70(Suppl 1):346-P, 2021.

63. Battelino, T., Bailey, T.S., Tehranchi, R., Klaff, L.J., Pieber, T., Hövelmann U., Plum-Mörschel, L., Melgaard, A., Aronson, R., Dimeglio, L., Danne, T.
The next-generation glucagon analog dasiglucagon consistently achieves rapid recovery from hypoglycemia across subgroups.
Diabetes 70(Suppl 1):345-P, 2021.

64. Heller, S.R., Battelino, T., Bailey, T.S., Tehranchi, R., Klaff, L.J., Pieber, T., Hövelmann, U., Plum-Mörschel, L., Melgaard, A., Aronson, R., Dimeglio, L., Danne, T.
Integrated safety analysis of dasiglucagon for treatment of severe hypoglycemia.
Diabetes 70(Suppl 1):344-P, 2021.

30th Annual Conference Asian Pacific Association for the Study of the Liver (APASL). Virtual, June 4–6, 2021

65. Flint, A., Andersen, G., Hockings, P., Johansson, L., Ersbøll, A., Sundby Palle, M.S., Vogl, T.J., Plum-Mörschel, L.
Semaglutide treatment in subjects with NAFLD: effects assessed by magnetic resonance elastography and magnetic resonance imaging proton density fat fraction.



Advanced Training Courses

Training for the Clinical Trial Recruitment Team

66. Dr. Sabine Arnolds
Profil GmbH, Neuss, Germany
NAFLD study results.
December 6, 2021

67. Dr. Sabine Arnolds
Profil GmbH, Neuss, Germany
COVID-19 vaccines clinical trials
February 1, 2021

Trainings Clinical Pharmacology

68. Dr. Grit Andersen
Profil GmbH, Neuss, Germany
Basics of clinical evaluation: Clinical documentation structure of a test plan.
December 16, 2021

69. Dr. Susanne Otten
Profil Mainz GmbH & Co. KG, Mainz, Germany
Thrombosis and thromboembolism.
November 23, 2021

70. Prof Dr. Norbert Stefan
University Hospital, Tübingen, Germany
EASD Summary T2DM.
November 4, 2021

71. Prof Dr. Thomas Forst
CRS Clinical Research Services Management GmbH, Mannheim, Germany
EASD Summary T1DM.
October 28, 2021

72. Dr. Nadia Heramvand
University Hospital of Düsseldorf, Düsseldorf, Germany
Predictive PK model of Tirofiban.
August 26, 2021

73. Hsieh Chin-Yuan
Profil GmbH, Neuss, Germany
Diabetic Foot Syndrome.
March 4, 2021

74. Dr. Sabine Arnolds
Profil GmbH, Neuss, Germany
News about SARS-CoV-2 vaccines.
January 28, 2021

Awards and Appointments

75. **Among the most frequently downloaded articles (October 1– 1, 2021) published in Alimentary Pharmacology & Therapeutics**
Flint, A., Andersen, G., Hockings, P., Johansson, L., Morsing, A., Sundby Palle, M., Loomba, R., Vogl, T.J., Plum-Mörschel, L.
Randomized clinical trial: Semaglutide versus placebo reduced liver steatosis but not liver stiffness in subjects with non-alcoholic fatty liver disease assessed by magnetic resonance imaging.
Aliment. Pharmacol. Ther. 54(9):1150-1161, 2021
IF(2021): 8.171

ALIMENTARY PHARMACOLOGY & THERAPEUTICS

Edited by Professor C. W. Howden and Professor R. Loomba

Doris Edwards, Editorial Manager
e-mail: dorisedwards.apt@gmail.com

APT-0812-2021.R2

17th November 2021

Anne Flint
Novo Nordisk A/S
Vandtårnsvej 114
DK-2860 Søborg
Denmark

aflt@novonordisk.com

Dear Ms Flint

We are delighted to let you know that your paper ***"Randomised clinical trial: semaglutide versus placebo reduced liver steatosis but not liver stiffness in subjects with non-alcoholic fatty liver disease assessed by magnetic resonance imaging"*** was in the top electronic downloads between 1st October and 31st October 2021 of recent articles published in *AP&T*.

Click here to view the complete list of top downloaded manuscripts.

Many congratulations!

As ever, very many thanks for sending your interesting work to *AP&T* - please send some more!

Yours sincerely

Professor Colin W Howden
Editor

Professor Rohit Loomba
Editor

Granted Innovation Activities

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

Profil is represented in the EIT Health Germany GmbH Supervisory Board.
https://eit-health.de/wp-content/uploads/2021/01/EIT_Health_Aufsichtsraete.pdf
https://eit-health.de/team/

77. **EIT Health Health innovation project**
CLOSE: Automated Glucose Control at Home for People with Chronic Disease.

Members & guests of the CLOSE Consortuim. Barcelona, September 2019.

Project duration: up to December 2023
Funding period: July 2016 – December 2019
Involved EIT Health partners: Air Liquide Healthcare, Sanofi, Profil GmbH, IESE Business School, Katholic University Leuven, Medical University of Lodz.
Additional project partners: Aqua Institute for Applied Quailty Improvement and Research in Health Care GmbH, European Research and Project Office GmbH
Coordinating organisation: Profil GmbH
https://www.eithealth.eu/en_US/close
http://eit-health.de/activities/innovation-projects/close-diabetes/
J. Diabetes Sci. Technol. 13(2):261-267, 2019
https://journals.sagepub.com/doi/pdf/10.1177/1932296818803588
https://diatec-fortbildung.de/aid-fuer-menschen-mit-typ-2-diabetes-die-pan-europaeische-close-initiative/

78. **EIT Health innovation project:**
iPDM-GO: Integrated Personalized Diabetes Management (iPDM) Goes Europe.

Funding period: January 2019 – December 2021
Involved partners: Roche Diabetes Care, Profil, German Center for Diabetes Research, University of Copenhagen, Danmarks Tekniske Universitet, Helmholtz Center Munich, City of Copenhagen, Capital Region of Denmark, LINQ management
Coordinating organisation: Roche Diabetes Care
https://eithealth.eu/project/ipdm-go/
https://eit-health.de/en/ipdm-go/
https://eit-health.de/ipdm-go/
Primary Care Diabetes 15(2):360-364, 2021
https://www.primary-care-diabetes.com/action/showPdf?pii=S1751-9918%2820%2930293-X

79. **EIT Health Innovation project**
RealWorld4Clinic: Real-World Cardio-Respiratory Health Monitoring for Clinical Contract Research & Telecardiology

Funding period: January 2020 – December 2022
Involved partners: Profil, SentinHealth, Fraunhofer Institute for Toxicology and Experimental Medicine, University Grenoble Alpes, Inserm, RWTH Aachen, RWTH Aachen University Hospital, CHU Grenoble Alpes, CHU de Rennes, Grenoble École de Management, MADoPA, Zana Technologies, PrYv, Aqua Institute for Applied Quailty Improvement and Research in Health Care (aQua), SurgiQual Institute, LINQ management
Coordinating organisation: Profil
https://eithealth.eu/project/realworld4clinic/
https://eit-health.de/en/realworld4clinic/
https://eit-health.de/realworld4clinic/

Scientific Communication

Online Seminars

https://www.profil.com/knowledge-center/online-seminars

80. **Advancements in oral insulin development: are we nearly there yet?**
E. Zijlstra. November 2, 2021.

81. **Once-weekly insulins.**
J. H. de Vries. August 3, 2021.

82. **IMP manufacturing services for multi and single-centre clinical trials in EU.**
P. Mozaffari. May 05, 2021.

83. **Audit trail review in clinical studies using virtual data analytics**.
S. Heckermann. March 23, 2021.

Blogs

http://blog.profil.com/blog

84. **A pathophysiological update of the incretins.**
U. Hövelmann. December 13, 2021

85. **GLP-1 agonists: An option for NAFLD?**
G. Andersen. November 11, 2021

86. **"Profil World" – The clinical diabetes research newsletter October 2021.**
M. Andresen. October 13, 2021

87. **Announcement Free Online Seminar: Advancements in oral insulin development.**
M. Andresen. October 5, 2021

88. **Oral insulin: The future of insulin therapy?**
S. Arnolds. September 23, 2021

89. **EU Clinical Trials Regulation (EU-CTR) enters application on 31 January 2022.**
G. Andersen. August 9, 2021

90. **"Profil World" – The clinical diabetes research newsletter July 2021**.
M. Andresen. July 12, 2021

91. **Can remote decentralised clinical trials enhance clinical research?**
F. Schliess. June 2, 2021

92. **Gender ratio in clinical trials – are there less female trial participants?**
S. Arnolds. May 7, 2021

93. **Announcement Free Online Seminar: IMP manufacturing services for clinical trials in EU.**
M. Andresen. April 22, 2021

94. **Reporting of study results: a challenge?**
G. Andersen. April 6, 2021

"Profil World" – The clinical diabetes research newsletter March 2021.
M. Andresen. March 16, 2021

95. **Profil leads the way in establishing audit trail review procedures in clinical studies using visual data analytics.**
S. Heckermann. March 8, 2021

96. **Free online seminar: audit trail review in clinical studies using visual data analytics.**
S. Heckermann. February 23, 2021

97. **Can serious games motivate teenagers with diabetes to adhere to their treatments?**
T. Dicenzo. February 9, 2021

98. **Running clinical trials at Profil during pandemic times.**
J. Villagra. January 7, 2021

Media Reports (Selection)

99. **Type 2 diabetes: Massive Kosteneinsparungen und verbesserte Lebensqualität durch automatisierte Verabreichung von Insulin**
November 2021
https://eit-health.de/typ-2-diabetes-massive-kosteneinsparungen-und-verbesserte-lebensqualitaet-durch-automatisierte-verabreichung-von-insulin/

100. **Diabetesmanagement: zum Experten für sich selbst werden.**
Profil Diabetes Ratgeber
November 2021
https://www.profil.de/blog/projekt-ipdm-go

101. **EIT Health Roundtable discussion: DiGAs – a model for Europe?**
Possible options for achieving a European system.
Statements from the EIT Health Germany Round-table held as part of the 16th Kassengipfel (health-insurer summit) on 16 September 2021 in Berlin
https://eit-health.de/wp-content/uploads/2022/01/EITHEA2.pdf

102. **STAT+ exclusive biopharma, health policy and life science analysis**
Artificial pancreases were a breakthrough for type 1 diabetes. The research in type 2 is just beginning
Katie Palmer
Ausgust 2021
https://www.statnews.com/2021/08/04/artificial-pancreas-type-2-diabetes-outpatient/?utm_source=researcher_app&utm_medium=referral&utm_campaign=RESR_MRKT_Researcher_inbound

103. **DiaTec Fortbildung**
Warum dauert die Entwicklung von „smarten“ (Glucose-sensitiven) Insulinen so lange?
Tim Heise
June 2021
https://diatec-fortbildung.de/warum-dauert-die-entwicklung-von-smarten-glucose-sensitiven-insulinen-so-lange/

104. **Start-ups Meet Pharma 2021 officially kicks off with Module One.**
8 days, 13 workshops, 18 teams, 10 amazing speakers and Module 1 of Start-ups Meet Pharma 2021 is over!
June 2021
https://eit-health.de/en/start-ups-meet-pharma-2021-officially-kicks-off-with-module-one/

105. **The Mentoring & Coaching Network**
A Triple Win for Counsellors, Start-ups and EIT Health
Freimut Schliess
June 2021
https://eit-health.de/en/the-mentoring-coaching-network-a-triple-win-for-counsellors-start-ups-and-eit-health-freimut-schliess/

106. **Think Tank 2020 Round Table Series: German Think Tank Report**
The EIT Health Think Tank 2020 drove analysis into the potential of AI to transform healthcare across multiple European regions, and provided recommendations for greater acceptance and utility of AI within the field.
January 2021
https://eit-health.de/en/think-tank-2020-round-table-series-german-think-tank-report/