



# Science Report 2020



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Lead Scientist  
Chairman of the Board of Directors  
Co-Founder of Profil

## Preface

*“Bad times have a scientific value.  
These are occasions a good  
learner would not miss.”*  
Ralph Waldo Emerson  
(1803-1882)

If you believe in the statement of the American philosopher Ralph Waldo Emerson above, 2020 was certainly one of the best years for science. Indeed, never before were the merits, but also the challenges of science discussed as lively in the general public. Many publications on COVID-19 even when just being submitted for open-peer-review generated top headlines in daily newspapers. Diabetes researchers might have envied their peers in virology for their new popularity, but virologists quickly had to realise that this popularity comes at a price. Many had to correct themselves multiple times with the appearance of new research data, and despite a steep learning curve and literally thousands of publications there are still countless questions on COVID-19 science has not been able to answer.

While the focus on virology in the past year is very understandable, there is always a risk that other important research topics are neglected. Indeed, diabetes research has not been easy since the start of the pandemic. Communication among scientists has been hampered by not being able to meet each other at scientific meetings. Communication within a research team

has not exactly become any easier with many people working in home office. Clinical studies have become more difficult with social distancing and other protective measures from infectious diseases. Therefore, I am particularly proud to present the publication output of Profil scientists in this Science Report, and to report that, despite all difficulties, the number of publications and the mean impact factor increased in 2020 compared to previous years. We published 30 scientific papers and 6 letters and book chapters with a cumulated impact factor of nearly 212 (versus 150 in 2019). Our publications covered a wide range of topics with the usual focus on new drugs and devices, but also addressing patient needs, management of patients with COVID-19, exercise and improvements of important research methods such as flow-mediated dilatation.

Details are given in this Science Report which was, as always, meticulously compiled by Prof Freimut Schliess and his team. We hope that our scientific publications and presentations are a small contribution to the overall goal of improving diabetes therapy and the life quality of people with diabetes. The past year showed once again how important these goals are to converge the life expectancy of people with diabetes to those of people without diabetes, and to reduce the excess mortality, not only from COVID-infections, but in particular from cardiovascular disease.

There is still a long way to go to achieve these goals, but the development of newer anti-diabetic agents with improved cardiovascular outcomes certainly is a step in the right direction. More are going to come, and we at Profil are proud to be a small part of these improvements.

Let me conclude by expressing my sincere gratitude to the whole Profil team where each and everybody contributed to the great scientific success illustrated in this report. My heartfelt thanks also go to our study participants. Without their commitment and their support, our work would not have been possible.



Image: <https://www.istockphoto.com/de/portfolio/wavebreakmedia>

# Content

<b>Science Report 2020</b> .....	1
<b>Preface</b> .....	2
<b>Content</b> .....	5
<b>Metrics</b> .....	6
<b>Scientific Publications</b> .....	8
Original articles.....	8
Reviews.....	14
Books/Letters/Comments.....	15
<b>Scientific Congress Presentations</b> .....	17
Oral presentations.....	17
Poster presentations.....	21
<b>Advanced Training Courses</b> .....	24
Science circle.....	24
Training for the clinical trial recruitment team.....	24
Trainings clinical pharmacology.....	25
Awards and appointments.....	27
<b>Granted Research Consortia</b> .....	28
<b>Scientific Communication</b> .....	32
Online Seminars.....	32
Blogs.....	33
Media appearance (selection).....	36

## Metrics

**TABLE 1: TOTAL OUTPUT**

	Count	$\Sigma$ Impact Factors	Mean Impact Factor
<b>Scientific Publications</b>	<b>36</b>	<b>211,92</b>	<b>7,06</b>
Original Articles	26	194,30	7,47
Reviews	4	17,62	4,41
Books/Letters/Comment	6	0,00	0,00
<b>Scientific Congress Presentations</b>	<b>32</b>	n/a	n/a
Orals	22	n/a	n/a
Poster	10	n/a	n/a
<b>Advanced Trainings</b>	<b>17</b>	n/a	n/a
<b>Granted Research Consortia</b>	<b>3</b>	n/a	n/a
<b>Scientific Communication</b>	<b>39+</b>	n/a	n/a
Online Seminars	3	n/a	n/a
Blog Posts	22	n/a	n/a
Media Appearance	14+	n/a	n/a

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

	Count	$\Sigma$ Impact Factors	Mean Impact Factor
<b>Scientific Publications</b>	<b>16</b>	<b>42,73</b>	<b>4,27</b>
Original Articles	9	38,13	4,12
Reviews	1	4,60	4,60
Books/Letters/Comment	6	0,00	0,00
<b>Scientific Congress Presentations</b>	<b>22</b>	n/a	n/a
Orals	16	n/a	n/a
Poster	6	n/a	n/a

**TABLE 3: PUBLISHED STUDIES (PARTLY) OPERATED BY PROFIL**

	Count	$\Sigma$ Impact Factors	Mean Impact Factor
<b>Scientific Publications</b>	<b>19</b>	<b>116,69</b>	<b>6,14</b>
Original Articles	19	116,69	6,14
Reviews	n/a	n/a	n/a
Letters/Comments	n/a	n/a	n/a
<b>Scientific Congress Presentations</b>	<b>25</b>	n/a	n/a
Orals	15	n/a	n/a
Poster	10	n/a	n/a

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

	Count	$\Sigma$ Impact Factors	Mean Impact Factor
<b>Scientific Publications</b>	<b>9</b>	<b>38,13</b>	<b>4,24</b>
Original Articles	9	38,13	4,42
Reviews	n/a	n/a	n/a
Letters/Comments	n/a	n/a	n/a
<b>Scientific Congress Presentations</b>	<b>19</b>	n/a	n/a
Orals	14	n/a	n/a
Poster	5	n/a	n/a

# Scientific Publications

## Original articles

1. Herbrand, T.,<sup>1</sup> Coester, H.V., Sansone, R., Fischer, A., Heiss, C., Heise, T., Kelm, M., DeVries, H.J.  
Improving the assessment of flow-mediated dilation through detection of peak time in healthy subjects and subjects with type 2 diabetes.  
**Angiology** 2020 Dec 30, doi:10.1177/0003319720984884  
**IF(2020): 2,25**
2. 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.** 2020 Dec 18, doi:10.1111/dom.14302  
**IF(2020): 5,48**
3. Hulst, A.H., Polderma, J., 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.** 2020 Dec 16, doi:10.1016/j.bja.2020.10.023  
**IF(2020): 6,88**
4. Stegbauer, C., Falivena, C., Moreno, A., Hentschel, A., Rosenmöller, M., Heise, T., Szecsenyi, J., Schliess, F.  
Costs and its drivers for diabetes mellitus type 2 patients in France and Germany: A systematic review of economic studies.  
**BMC Health Serv. Res.** 20(1):1043, 2020  
**IF(2020): 2,51**

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<sup>1</sup>Underlined: authors from Profil



5. Leohr, J., Dellva, M.A., Coutant, D.E., LaBell, E., Heise, T., Andersen, G., Zijlstra, E., Hermanski, L., Nosek, L., Linnebjerg, H.  
Pharmacokinetics and glucodynamics of ultra rapid lispro (URLi) versus Humalog® (Lispro) in patients with type 2 diabetes mellitus: A phase I randomised, crossover study.  
**Clinical Pharmacokinet.** 59(12):1601-1610, 2020  
**IF(2020): 4,86**
  
6. Ólafsdóttir, 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.** 2020 Dec 10, doi:10.1111/dom.14257  
**IF(2020): 5,48**
  
7. Gruchala, A., Cypryk, K., Schliess, F., Bobeff, K., Heise, T., Gurdala, M., Szadkowska, A., Mianowska, B.  
Pains and needs of patients with type 2 diabetes as targets for novel technologies.  
**Clinical Diabetology** 9(6):400-410, 2020  
**IF(2020): 0,15**
  
8. Huang, J., Huth, C., Covic, M., Troll, M., Adam, J., Zukunft, S., Prehn, C., Wang, L., Nano, J., Scheerer, M.F., Neschen, S., Kastenmüller, G., Suhre, K., Laxy, M., Schliess, F., Gieger, C., Adamski, J., Hrabe de Angelis, M., Peters, A., Wang-Sattler, R.  
Machine learning approaches reveal metabolic signatures of incident chronic kidney disease in individuals with prediabetes and type 2 diabetes.  
**Diabetes** 69(12):2756–2765, 2020  
**IF(2019): 7,72**
  
9. 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.** 2020 Nov 25, doi: 10.1111/dom.14260  
**IF(2020): 5,48**

10. 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** 2020 Nov 15. doi:10.2337/dc20-1468  
**IF(2020): 16,02**
  
11. 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** 2020 Nov 12, doi:10.2337/dc20-1496  
**IF(2020): 16,02**
  
12. 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., Kiirkesseli, 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.** 2020 Nov 26, doi:10.1111/bcp.14632  
**IF(2019): 3,74**
  
13. Heise, T., Linnebjerg, H., Coutant, D., LaBell, E., Zijlstra, E., Kapitza, C., Bue-Valleskey, J., Zhang, Q., Dellva, M.A., Leohr, J.  
Ultrarapid lispro lowers postprandial glucose and more closely matches normal physiological glucose response compared to other rapid insulin analogues: A phase 1 randomized, crossover study.  
**Diabetes Obes. Metab.** 22(10):1789-1798, 2020  
**IF(2020): 5,48**
  
14. Andersen, G., Plum-Mörschel, L., Hockings, P.D., Morsing, A., Palle, M.S., Svolgaard, O., Flint, A.  
Clinical characteristics of a non-alcoholic fatty liver disease population across the fibrosis spectrum measured by magnetic resonance elastography: Analysis of screening data.  
**Adv. Ther.** 37(12):4866-4876, 2020  
**IF(2019): 3,87**

15. Ahmadi, S.S., Westman, K., Pivodic, A., Ólafsdóttir, A.F., Dahlqvist, S., Hirsch, I.B., Hellman, J., Ekelund, M., Heise, T., Polonsky, W., Wijkman, M., Schwarcz, E., Lind, M.  
The association between HbA<sub>1c</sub> and time in hypoglycemia during CGM and self-monitoring of blood glucose in people with type 1 diabetes and multiple daily insulin injections: A randomized clinical trial (GOLD-4).  
**Diabetes Care** 43(9):2017-2024, 2020  
**IF(2020): 16,02**
  
16. Quast, D.R., Schenker, N., Menge, B.A., Nauck, M.A., Kapitza, C., Meier, J.J.  
Effects of lixisenatide versus liraglutide (short- and long-acting GLP-1 receptor agonists) on esophageal and gastric function in patients with type 2 diabetes.  
**Diabetes Care** 43(9):2137-2145, 2020  
**IF(2020): 16,02**
  
17. Leohr, J., Dellva, M.A., LaBell, E., Coutant, D.E., Klein, O., Plum-Mörschel, L., Zijlstra, E., Linnebjerg, H.  
Pharmacokinetic and glucodynamic responses of ultra rapid lispro vs lispro across a clinically relevant range of subcutaneous doses in healthy subjects.  
**Clin. Ther.** 42(9):1762-1777, 2020  
**IF(2020): 3,12**
  
18. Suico, J.G., Hövelmann, U., Zhang, S., Shen, T., Bergman, B., Sherr, J., Zijlstra, E., Frier, B.M., Plum-Mörschel, L.  
Glucagon administration by nasal and intramuscular routes in adults with type 1 diabetes during insulin-induced hypoglycaemia: A randomised, open-label, crossover study.  
**Diabetes Ther.** 11(7):1591-1603, 2020  
**IF(2020): 3,18**
  
19. Bornstein, S.R., Rubino, F., Khunti, K., Mingrone, G., Hopkins, D., Birkenfeld, A.L., Boehm, B., Amiel, S., Holt, R.I., Skyler, J.S., DeVries, J.H., Renard, E., Eckel R.H., Zimmet, P., Alberti, K.G., Vidal, J., Geloneze, B., Chan, J.C., Ji, L., Ludwig, B.  
Practical recommendations for the management of diabetes in patients with COVID-19.  
**Lancet Diabetes Endocrinol.** 8(6):546-550, 2020  
**IF(2019): 25,34**

20. Linnebjerg, H., Zhang, Q., LaBell, E., Dellva, M.A., Coutant, D.E., Hövelmann, U., Plum-Mörschel, L., Herbrand, T., Leohr J.  
Pharmacokinetics and glucodynamics of ultra rapid lispro (URLi) versus Humalog® (lispro) in younger adults and elderly patients with type 1 diabetes mellitus: A randomised controlled trial.  
**Clin. Pharmacokinet.** 59(12):1589-1599, 2020  
**IF(2019): 4,60**
21. Heise, T., Donnelly, C., Barve, A., Aubonnet, P.  
Pharmacokinetic and pharmacodynamics bioequivalence of proposed biosimilar MYL-1501D with US and European insulin glargine formulations in patients with type 1 diabetes mellitus.  
**Diabetes Obes. Metab.** 22(4):521-529, 2020  
**IF(2020): 5,48**
22. Kapitza, C., 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. Ther.** 22(4):278-284, 2020  
**IF(2019): 4,40**
23. 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.** 22(4):599-611, 2020  
**IF(2020): 5,48**
24. 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, 2020  
**IF(2020): 3,46**

25. Parker, V.E.R., Robertson, D., Wang, T., Hornigold, D.C., Petrone, M., Cooper, A.T., Posch, M.G., Heise T., Plum-Mörschel, L., Schlichthaar, H., 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.** 105(3):803-820, 2020  
**IF(2019): 5,24**
  
26. Leelarathna, L., Thabit, H., Willinska, M.E., Bally, L., Mader, J.K., Arnolds, S., Benesch, C., Pieber, T.R., Shah, V.N., Carlson, A.L., Bergenstal, R.M., Evans, M.L., Hovorka, R., AP@home04 and APCam11 consortia.  
Duration of hybrid closed-loop insulin therapy to achieve representative glycemic outcomes in adults with type 1 diabetes.  
**Diabetes Care** 43(3):e38-e39, 2020  
**IF(2020): 16,02**

## Reviews

27. 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., Mattieu, C., Mader, J.K.  
Glucose management for exercise using continuous glucose monitoring (CGM) and intermittently scanned CGM (isCGM) systems in type 1 diabetes: Position statement of the European Association for the Study of Diabetes (EASD) and of the International Society for Pediatric and Adolescent Diabetes (ISPAD) endorsed by JDRF and supported by the American Diabetes Association (ADA). **Diabetologia** 63(12): 2501–2520, 2020  
**IF(2019): 7,51**
28. 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.  
**Primary Care Diabetes** 2020 Nov 9, doi:10.1016/j.pcd.2020.10.008  
**IF(2020): 2,05**
29. Haahr, H., Heise, T.  
Fast-acting insulin aspart: A review of its pharmacokinetic and pharmacodynamic properties and the clinical consequences.  
**Clin. Pharmacokinet.** 59(2):155-172, 2020  
**IF(2019): 4,60**
30. Han, J., Heinemann, L., Ginsberg, B.H., Alva, S., Appel, M., Bess, S., Chen, K.Y., Freckmann, G., Harris, D.R., Hartwig, M., Hinzmann, R., Kerr, D., Krouwer, J., Morrow, L., Nichols, J., Pfützner, A., Pleus, S., Rice, M., Sacks, D.B., Schlueter, K., Vesper, H.W., Klonoff, D.C.  
The YSI 2300 analyzer replacement meeting report.  
**J. Diabetes Sci. Technol.** 14(3):679-686, 2020  
**F(2020): 3,46**

## Books/Letters/Comments

31. Affini-Dicenzo, T., Schliess, F.  
Bridging the gap between clinical trials and clinical care.  
**Open Access Government**  
Technology eBook  
September 28, 2020  
**IF:-**
32. Schliess, F.  
Continuous real-world monitoring of cardiorespiratory health.  
**Open Access Government**  
Special Health and Social Care Report  
September 2, 2020  
**IF:-**
33. Schliess, F.  
Digital twins: Are they game-changers in clinical research and clinical care?  
**Open Access Government** ISSN 2516-3817  
August 26, 2020  
**IF:-**
34. Schliess, F.  
A vision on remote decentralised clinical trials.  
**Open Access Government** ISSN 2516-3817  
July 17, 2020  
**IF:-**
35. Schliess, F.  
Think Tank highlights CROs key role in optimising innovation pathways.  
**Open Access Government** ISSN 2516-3817  
March 26, 2020  
**IF:-**
36. Schliess, F.  
Trustworthy artificial intelligence in healthcare: It's time to deliver.  
**Open Access Government.** SSN 2516-3817  
January 6, 2020  
**IF:-**

Bridging the gap  
between clinical trials  
and clinical care:  
Are wearables fit for this purpose?





## Scientific Congress Presentations



### Oral presentations

**20<sup>th</sup> Annual Diabetes Technology Meeting (DTM). Bethesda, USA, November 11 – 19, 2020**

37. Heise, T.  
Moderator: What is the role of ultra short acting and ultra long acting analog insulins?

**Joint EIT Health Germany & EIT Health Innostars Symposium: Value-Based Healthcare – Improving Outcomes for Patients around Europe. Mannheim, Germany, October 26 – 27, 2020**

38. Jacobsen, M., Dembek, T., Ziakos, A.-P., Gholamipour, R., Kobbe, G., Kollmann, M., Blum, C., Müller-Wieland, D., Napp, A., Heinemann, L., Sause, A., Deubner, N., Marx, N., Isenmann, S., Seyfarth, M.  
Reliable detection of atrial fibrillation with a medical wearable during inpatient conditions.

**20<sup>th</sup> International Conference on Integrated Care (ICIC). September 30, 2020**

39. Jones, A., Kownatka, D., Schliess, F., Vrangbæk, K.  
Integrated personalised diabetes management goes Europe: Co-creating approaches for better outcomes.

**EIT Health Think Tank, German Roundtable. September 22, 2020**

40. Diehl, A., Alexanderssen, J., Dehn, C., Heimann, T., Hoxha, J., Ionasc, R., Pförringer, D., Reiberg, D., Schliess, F., Stork, W., Wagner, C., Walter, J., Marin, M., Conning, S., Lüttgen, M., Ladewig, K.  
Healthcare workforce and organisational transformation with AI: Enacting change.  
**EIT Health Think Tank Round Table Meeting Procedures, 2020**

**56<sup>th</sup> European Association for the study of diabetes (EASD) Annual Meeting. Vienna, Austria, September 21 – 25, 2020**

41. Heise, T.  
Session chair: Insulin therapy: fast acting insulin analogues.  
**Diabetologia** 63(Suppl 1):PS57, 2020
42. Heise, T.  
How to ensure similarity: The regulatory pathway for biosimilar insulins.  
Meet the Expert Symposium – the biosimilar journey, past, present, and future.

**ECSEL JU - IMI JU Joint Session. June 18, 2020**

43. Schliess, F.,  
Real-world cardiorespiratory health monitoring for clinical research and telecardiology.

**5<sup>th</sup> Hello Diabetes Digital Academia. International Conclave. Symposium Novo Nordisk. India, July 17 – 19, 2020**

44. Heise, T.  
Hypoglycaemia in T2DM management: Making the most of new generation insulins.

**American Diabetes Association (ADA) 80<sup>th</sup>. Scientific Sessions. Chicago, USA.  
June 12 – 16, 2020**

45. Hövelmann, U., Brondsted, L., Kristensen, R.N., Ribel-Madsen, R., Ranson, A., DeVries, J.H., Heise, T., Haahr, H.  
Insulin icodec: An insulin analog suited for once-weekly dosing in type 2 diabetes.  
**Diabetes** 69 (Suppl. 1):237-OR, 2020
46. Mursic, I., Svehlikova, E., Regittnig, W., Augustin, T., Magnes, C., Eberl, A., Heise T., Klein, O., Wolf, M., Urschitz, M., Brunner, M., Sourij, H., Pieber, T.  
Acid-base changes during diabetes ketoacidosis (DKA) in T1DM with and without SGLT2 inhibitor (SGLT2i).  
**Diabetes** 69(Suppl. 1):25-OR, 2020
47. Lind, M., Olafsdottir, A.F., Hirsch, I.B., Bolinder, J., Dahlqvist, S., Pivodic, A., Hellman, J., Wijkman, M.O., Schwarcz, E., Albrektsson, H., Heise, T., Polonsky, W.  
Sustained intensive treatment and long-term effects on A1C reduction (Silver study) by CGM in persons with T1D treated with MDI.  
**Diabetes** 69(Suppl. 1):64-OR, 2020

**4<sup>th</sup> International Quality Improvement Forum. 11 – 12 June 2020, Heidelberg, Germany**

48. Schliess, F., Dopierala, C., Parmentier, T., de Marco, S., Frierip, U., Jacobsen, M., Schütt, K., Stegbauer, C., Hentschel, A., Hoxha, J., Recorbet, F., Broge, B., Szecsenyi, J., Lemaire, M., Müller-Wieland, D., Marx, N., Cinquin, P., Ruling, C.-C., Plum-Mörschel, L., Heckermann, S., Heinemann, L., Heise, T.  
Digital tools for narrowing the gap between clinical research and clinical care.

**Novo Nordisk “Lighthouse” Meeting. April 2, 2020**

49. Heise, T.  
The future of basal insulin

**10<sup>th</sup> Operational Excellence in Clinical Trials Summit – Study Feasibility and Patient Recruitment Retention. 3 – 5 March 2020, Munich, Germany**

50. Schliess, F.  
Clinical contract research: A digital bridge between clinical research and clinical care.
51. Mc Donald, D., Linz, N., Schliess, F., Frutsch, F., Daemen, E.  
Interactive panel discussion: Role of technologies in clinical innovation.

**13<sup>th</sup> International Conference on Advanced Technologies and Treatments for Diabetes (ATTD).  
Madrid, Spain, February 19 – 22, 2020**

52. DeVries, J.H.  
Session chair: Adjunctive therapies for type 1 diabetes.  
**Diabetes Technol. Ther.** 22(S1):A-4, 2020
53. Heise, T.  
How early is URLi (Ultra Rapid Lispro)?  
**Diabetes Technol. Ther.** 22(S1):A-15, 2020
54. Heise, T.  
Session chair: Oral presentation session 03.  
**Diabetes Technol. Ther.** 22(S1):A-23, 2020
55. Heinemann, L.  
Where do we go with SMBG and CGM?  
**Diabetes Technol. Ther.** 22(S1):A-8, 2020

**Diabetes support group Dormagen. Dormagen, Germany, February 3, 2020**

56. Arnolds, S.  
Diabetes research: New approaches.

**DiaTec 2020. Partner Symposium Novo Nordisk: Innovative therapy solutions for diabetes  
practice. Berlin, Germany. January 24 – 25, 2020**

57. Zijlstra, E.  
New tools in diabetes therapy.

**NRNW Medicine Update Congress. Neuss, Germany, January 24, 2020**

58. Arnolds, S.  
Diabetes research: A look into the future.

## Poster presentations

AASLD Liver Meeting Digital Experience, November 13 – 16, 2020

59. Flint, A., Andersen, G., Hockings, P., Johansson, L., Ersbøll, A., 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.

### Semaglutide treatment in subjects with NAFLD: effects assessed by magnetic resonance elastography and magnetic resonance imaging proton density fat fraction

Anne Flint,<sup>1</sup> Grit Andersen,<sup>2</sup> Paul Hockings,<sup>3,4</sup> Lars Johansson,<sup>3</sup> Anne Ersbøll,<sup>1</sup> Mads Sundby Palle,<sup>1</sup> Thomas J Vogl,<sup>5</sup> Leona Plum-Moerschel<sup>6</sup>

<https://eog-digital.com/a/aasld3022-flint/>

## Semaglutide significantly reduced liver fat in subjects with NAFLD, suggesting a positive impact on disease activity and metabolic profile

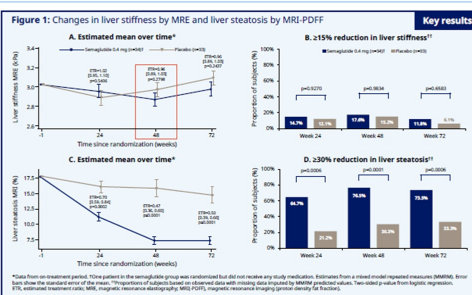
#### Aim

- Non-alcoholic fatty liver disease (NAFLD) is thought to be the liver manifestation of metabolic syndrome.<sup>1</sup> Accumulating data are emerging regarding the beneficial effects of glucagon-like peptide-1 receptor agonists (GLP-1RA) in patients with NAFLD.<sup>2,3</sup> Among GLP-1RAs, semaglutide has the most pronounced effect on body weight (BW).<sup>4</sup>
- This study investigated the effect of semaglutide on NAFLD, using non-invasive magnetic resonance imaging (MRI) methods and exploratory biomarkers.

#### Methods

- Subjects aged 18–75 years were included if they had:
  - NAFLD (MRI proton density fat fraction (MRI-PDF)  $\geq 10\%$ )
  - increased liver stiffness (magnetic resonance elastography (MRE) 2.50–4.63 kPa)
  - body mass index 25–40 kg/m<sup>2</sup>
  - glycated hemoglobin (HbA<sub>1c</sub>)  $\geq 5.5$  (with or without type 2 diabetes).
- Subjects were not biopsy-proven to have non-alcoholic steatohepatitis (NASH).
- Subjects were randomized 1:1 to subcutaneous (s.c.) semaglutide 0.4 mg/day or placebo for 72 weeks. Subjects were allowed nutritional and physical activity counselling but were not permitted to participate in an organized weight reduction program.
- The primary endpoint was change from baseline to week 48 in liver stiffness, assessed by MRE. Key secondary endpoints included MRE-assessed liver stiffness at 24 and 72 weeks, and liver fat content assessed by MRI-PDF at 24, 48, and 72 weeks.
- Changes in liver volume, visceral and s.c. abdominal fat (by MRI), liver enzymes (ALT, AST, GGT), and exploratory blood-based biomarkers for NASH were also measured along with FibroScan<sup>®</sup>, BW, and metabolic parameters.
- Scan the QR code or visit the web page (top right) for more details on the trial design.

#### Key results



- Of the 34 and 33 subjects randomized to s.c. semaglutide 0.4 mg and placebo, respectively, 27 (79.4%) and 30 subjects (90.9%) completed the trial.
- There was no significant difference in liver stiffness by MRE between the semaglutide and placebo groups at week 48 (primary endpoint) or at weeks 24 and 72 (Figure 1A).
- There was no difference between groups in the proportion of subjects with  $\geq 15\%$  decrease in MRE (indicating decreased fibrosis) (Figure 1B). Fewer subjects had a  $\geq 15\%$  increase in MRE with semaglutide compared with placebo at week 72 (1 v 9).
- At week 48, the semaglutide group had a 53% placebo-adjusted reduction in liver steatosis which was maintained to week 72 (Figure 1C). Over 70% of subjects in the semaglutide group had a  $\geq 30\%$  reduction in liver steatosis at weeks 48 and 72 (Figure 1D).
- At weeks 24, 48, and 72, total liver volume, liver fat volume, visceral and s.c. abdominal fat volumes were reduced with semaglutide compared with placebo ( $p < 0.0001$  for all). FibroScan<sup>®</sup> results were in line with MRI results.
- Relative to placebo, semaglutide treatment led to BW loss of 10% ( $p < 0.0001$ ), HbA<sub>1c</sub> decrease of 1% points ( $p < 0.0001$ ; subjects with type 2 diabetes), and decreases in liver enzymes of 18–28% ( $p < 0.05$ ).
- Biomarkers of inflammation decreased with semaglutide treatment.
- Safety and tolerability were consistent with previous observations for semaglutide and other GLP-1RAs.
- Premature discontinuation due to an adverse event occurred in 1 subject (3.0%) in the semaglutide group and no subjects in the placebo group.
- Scan the QR code or visit the web page (top right) for more details on the trial results.

#### Conclusion

- No apparent improvement in liver stiffness was observed after semaglutide treatment.
- Semaglutide significantly reduced liver fat which, together with other findings, suggests a positive impact on NASH-related disease activity and metabolic profile in subjects with NAFLD.

<sup>1</sup>Hesse NV, ACS, Sebarg, Denmark; <sup>2</sup>Profil, Næstved, Germany; <sup>3</sup>Metrolab Medical, Mölndal, Sweden; <sup>4</sup>MachPharm, Children's University of Technology, Gothenburg, Sweden; <sup>5</sup>University Hospital, Frankfurt, Germany; <sup>6</sup>Profil, Mainz, Germany. Anne Flint is an employee of and holds shares in Hesse Nordtal, ACS. This trial was sponsored by Hesse Nordtal and is registered with ClinicalTrials.gov (NCT03873789). The authors acknowledge the medical writing assistance of Andy Biondi (Opti Medical Communications Group LLC). Presented at the AASLD Liver Meeting Digital Experience, November 13–16, 2020.

56<sup>th</sup> European Association for the Study of Diabetes (EASD) Annual Meeting. Vienna, Austria, September 21 – 25, 2020

60. Hövelmann, U., Brondsted, L., Kristensen, N.R., Ribel-Madsen, R., DeVries, J.H., Heise, T., Haahr, H.  
Insulin Icodec: an insulin analogue suited for once-weekly dosing in type 1 diabetes.  
*Diabetologia* 63 (Suppl 1):656, 2020

61. Mursic, I., Svehlikova, E., Regittnig, W., Urschitz, M., Wolf, M., Brunner, M., Augustin, T., Magnes, C., Eberl, A., Heise, T., Klein, O., Sourij, H., Pieber, T. Acid-base changes during diabetic ketoacidosis in type 1 diabetes with/without SGLT2 inhibitor.  
**Diabetologia** 63 (Suppl 1):567, 2020
62. Aronson, R., Pieber, T., Hövelmann, U., Willard, J., Plum-Mörschel, L., Knudsen, K.M., Tehranchi R. Ready-to-use dasiglucagon injection as a fast and effective treatment for severe hypoglycaemia.  
**Diabetologia** 63 (Suppl 1):733, 2020

**American Diabetes Association (ADA) 80th Scientific Sessions. Chicago, USA, June 12 – 16, 2020**

63. Robertson, D., Hansen, L., Jain, M., Parker, V., Petrone, M., Wang, T., Heise, T., Jermutus, L. Cotadutide (MEDI0382), a dual receptor agonist with glucagon-like peptide-1 and glucagon activity, is well tolerated (<600 mg) with robust effects on blood glucose in patients with T2DM.  
**Diabetes** 69 (Suppl 1):951-P, 2020
64. Zijlstra, E., Andersen, G., Plum-Mörschel, L., Rhodes, M., Patton, R., Bueche, B., Kuo, M.C., Le, T.H., Stedman, B.J., Patton, J.S. Variability of 501 inhaled insulin absorption and action.  
**Diabetes** 69 (Suppl 1):1019-P, 2020
65. 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 coformulation of pramlintide (PRAM) and insulin A21G, improves postprandial glucose vs. Novolog in type 1 diabetes (T1D).  
**Diabetes** 69 (Suppl 1):112-LB, 2020.

**13<sup>th</sup> International Conference on Advanced Technologies and Treatments for Diabetes (ATTD). Madrid, Spain, February 19 – 22, 2020**

66. DeVries, H.J., Razaqat Ali Qureshi, M., Zijlstra, E., Plum-Mörschel, L., Handy, C.M., Love, B., Chaudhry, S. A proof-of-concept study of a novel non-invasive glucose monitor  
**Diabetes Technol. Ther.** 22 (S1):A-62, 2020

67. 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, H.J. Ado09, a co-formulation of the amylin analog pramlintide and the A21g human insulin analog, lowers postprandial blood glucose versus insulin lispro in type 1 diabetes (T1D) new medications for treatment of diabetes.  
**Diabetes Technol. Ther.** 22 (S1):A-187, 2020
68. Pieber, T., Tehranchi, R., Hövelmann, U., Willard, J., Plum-Mörschel L., Aronson, R.  
Ready-to-use dasiglucagon injection as a fast and effective treatment for severe hypoglycemia: New medications for treatment of diabetes.  
**Diabetes Technol. Ther.** 22 (S1):A -189, 2020

## Advanced Training Courses

### Science circle

- 69. Dr. Grit Andersen  
Profil GmbH, Neuss, Germany  
**Pramlintide.**  
March 10, 2020
- 70. Ulrike Hövelmann  
Profil GmbH, Neuss, Germany  
**Insulin once a week.**  
March 10, 2020
- 71. Dr. Eric Zijlstra  
Profil GmbH, Neuss, Germany  
**Inhaled Insulin Studies.**  
March 10, 2020
- 72. Prof. Dr. Hans deVries  
Profil GmbH, Neuss, Germany  
**Ultimately a non-invasive CGM?**  
March 10, 2020

### Training for the clinical trial recruitment team

- 73. Dr. Sabine Arnolds  
Profil GmbH, Neuss, Germany  
**Update about measurement methods and devices (HbA1c/SMBG/CGM/FGM/CSII/CL /AP).**  
December 7, 2020
- 74. Dr. Sabine Arnolds  
Profil GmbH, Neuss, Germany  
**Diabetic nephropathy.**  
November 9, 2020
- 75. Dr. Sabine Arnolds  
Profil GmbH, Neuss, Germany  
**Covid-19 and diabetes / gestational diabetes.**  
October 26, 2020



76. Dr. Sabine Arnolds  
Profil GmbH, Neuss, Germany  
**Comorbidities in diabetes.**  
October 12, 2020

## Trainings clinical pharmacology

77. Ulrike Hövelmann  
Profil GmbH, Neuss, Germany  
**Covid-19 & diabetes mellitus.**  
November 26, 2020
78. Dr. Grit Andersen  
Profil GmbH, Neuss, Germany  
**Translational medicine & transferability of animal studies.**  
October 22, 2020
79. Eugen Baumgärtner  
Profil Mainz GmbH & Co. KG, Mainz, Germany  
**General pharmacology: Pharmacokinetic absorption.**  
August 27, 2020
80. Dr. Sybille Dellweg  
Profil GmbH, Neuss, Germany  
**Neuropathic pain.**  
August 6, 2020
81. Dr. Grit Andersen  
Profil GmbH, Neuss, Germany  
**Ethical and legal basis for clinical drug testing on humans.**  
July 23, 2020
82. Dr. Grit Andersen/ Eugen Baumgärtner  
Profil GmbH, Neuss, Germany  
**Introduction of further training in clinical pharmacology.**  
June 25, 2020
83. Dr. Marcel Ermer  
Profil Mainz GmbH & Co. KG, Mainz, Germany  
**Pharmacotherapy of thyroid diseases: Part 2.**  
May 28, 2020

84. Dr. Grit Andersen  
Profil GmbH, Neuss, Germany  
**Pharmacogenetic research on antidiabetic therapy.**  
January 31, 2020
85. Dr. Marcel Ermer  
Profil Mainz GmbH & Co. KG, Mainz, Germany  
**Pharmacotherapy of thyroid diseases – Part 1.**  
January 30, 2020



## Awards and appointments

86. Prof. Dr. Leona Plum-Mörschel  
Honorary Professorship for Biosciences  
**Friedrich-Schiller University**  
Jena, Germany



## Granted Research Consortia

### 87. 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).  
Funding period: 2015 – 2027  
<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.

Profil GmbH & Co. KG is associated to EIT Health as a linked third party.

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



Members of the CLOSE Consortium. Barcelona, September 2019

*Project duration:* Up to 2023

*Project EIT Health-funded period:* July 2016 – December 2019.

*Clinical trial:* “Evaluation of a closed-loop insulin delivery system at home with tailored home care services in poorly controlled T2DM” (ClinicalTrials.gov Identifier: NCT04233229).

*Involved partners:* Air Liquide Healthcare, Aqua Institute for Applied Quality Improvement and Research in Health Care (aQua), Sanofi, Profil GmbH, IESE Business School, Katholic University Leuven, Medical University of Lodz, European Research and Project Office (EURICE) GmbH

*Coordinating organisation:* Profil GmbH

[https://www.eithealth.eu/en\\_US/close](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>

EIT Health innovation project

**Diabeloop for teens (D4Teens).**

*Funding period:* July 2019 – December 2020

*Involved partners:* Commissariat à l'énergie atomique et aux énergies alternatives - laboratoire d'électronique des technologies de l'information (CEA-Leti), Centre d'Études et de Recherches pour l'Intensification du Traitement du Diabète (CERITD), Karolinska Institute, Katholic University Leuven, Profil GmbH, Research Institute of Sweden (RISE), Diabeloop

*Coordinating organisation:* CEA-Leti

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



Members of the D4Teens Consortium. Paris, July 2019

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 GmbH, 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 2020 Nov 9, doi:10.1016/j.pcd.2020.10.008

<https://www.primary-care-diabetes.com/action/showPdf?pii=S1751-9918%2820%2930293-X>

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 GmbH, Profil Mainz GmbH & Co. KG, 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 Quality 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/>



Members of the RealWorld4Clinic Consortium. Grenoble, March 2020

## Scientific Communication

### Online seminars



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



**Join the free webinar:**  
**"Insulin Biosimilars: More focus than ever on Glucose Clamp Studies"**

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

88. **Profil – the leading CRO for metabolic research.**  
Dr. Lars Bochmann  
October 7, 2020
89. **Insulin biosimilars: More focus than ever on Glucose Clamp Studies.**  
Dr. Tim Heise  
May 19, 2020
90. **Early phase obesity research: How to measure outcomes of interest.**  
Dr. Daniela Lamers  
February 19, 2020.



## Blogs

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

91. **Profil World: The clinical diabetes research newsletter. December 2020.**  
Lars Bochmann  
December 17, 2020
92.  **$\beta$ 3-adrenoceptor agonist Mirabegron: A candidate anti-obesity drug?**  
Daniela Lamers  
December 1, 2020
93. **Once-weekly basal insulin analogue in clinical development.**  
Ulrike Hövelmann  
November 17, 2020
94. **Glycaemic control in type 1 diabetes: Effects of diabetes technology and socioeconomic status.**  
Susanne Famulla  
November 4, 2020
95. **“Profil World”: The clinical diabetes research newsletter. October 2020.**  
Lars Bochmann  
October 13, 2020
96. **Free Online Seminar: Profil – the leading CRO for metabolic research.**  
Lars Bochmann  
September 21, 2020



97. **Profil starts in-house production of tubing sets for ClampArt, reinforcing the quality of world-class glucose clamp trials.**  
Carsten Benesch  
September 8, 2020
98. **The rollercoaster life of inhaled insulin.**  
Eric Zijlstra  
August 4, 2020
99. **Heart failure: SGLT2 inhibitors moving beyond diabetes.**  
Jorge Arrubla  
July 14, 2020
100. **Bringing the real world to clinical trial research: the use of wearables in pivotal clinical trials.**  
Tatiana Dicenzo  
June 23, 2020
101. **“Profil World”: The clinical diabetes research newsletter. June 2020.**  
Lars Bochmann  
June 2, 2020
102. **When artificial intelligence and artificial pancreas meet.**  
Oliver Klein  
May 26, 2020
103. **Non invasive CGM: hope at the horizon?**  
Hans DeVries  
May 6, 2020
104. **Free online seminar on insulin biosimilars.**  
Svenya Meister  
April 21, 2020
105. **Think Thank highlights CROs role in the adoption of AI-powered health innovation.**  
Freimut Schliess  
March 31, 2020
106. **Fighting Corona: Profil’s contribution.**  
Tim Heise  
March 20, 2020

107. **Clinical study shows better clamp quality with Clamp-PID algorithm.**  
Carsten Benesch  
March 17, 2020
108. **A novel method to determine the pharmacodynamics onset of action of prandial insulins.**  
Marc Stoffel  
March 3, 2020
109. **“Profil World”: The clinical diabetes research newsletter – February 2020.**  
Svenya Meister  
February 18, 2020
110. **Type 1 diabetes and mild cognitive impairment.**  
Grit Andersen  
February 4, 2020
111. **Free Online Seminar on early phase obesity research.**  
Svenya Meister  
January 21, 2020
112. **Trustworthy AI in healthcare: It’s time to deliver.**  
Freimut Schliess  
January 7, 2020



## Media appearance (selection)

- 113. **For the promotion of innovation at the interface of industry, research and education.**  
LinkedIn  
December 2020
- 114. **RealWorld4Clinic stakeholder workshop: Clinical Trials.**  
LinkedIn  
December 2020
- 115. **RealWorld4Clinic stakeholder workshop: Outpatient cardiology.**  
LinkedIn  
November 2020



- 116. **RealWorld4Clinic**  
RWTH Aachen University, EU projects in Horizon 2020  
October 2020
- 117. **Machine learning approaches revealed metabolic signatures of incident chronic kidney disease in persons with pre- and type 2 diabetes.**  
LinkedIn  
October 2020
- 118. **The resilience of clinical trial operations is a key factor for meeting agreed timelines in pivotal contract research.**  
LinkedIn  
October 2020
- 119. **Digital Twins hold huge opportunities for drug development and clinical medicine.**  
LinkedIn  
September 2020

120. **Remote Decentralized Clinical Trials (RDCT): Do they matter for pivotal clinical research?**  
LinkedIn  
August 2020
121. **Clinical trials for vaccine developers.**  
EIT Health Covid-19 Making connections  
March 26, 2020
122. **Profil supports vaccine development.**  
EIT Health Covid-19 News  
March 22, 2020
123. **Today more than ever: going ahead towards remote decentralized clinical trials.**  
LinkedIn  
March 2020
124. **Real-World Cardio-Respiratory Health Monitoring for Clinical Contract Research & Tele-Cardiology (RealWorld4Clinic).**  
aQua Institute Projects  
March 2020
125. **RealWorld4Clinic.**  
LINQ Management Projects & Fact Sheets  
March 2020
126. **Finding the right balance between innovation and protection with ethical guidelines for trustworthy AI.**  
EIT Health Germany  
January 2020