



ROeS- Nachrichten

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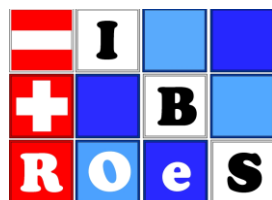
August 2018

ROeS-Nachrichten

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Welcome Address by the ROeS President

Dear ROeS members and colleagues,

Two years ago, Martin Posch started his welcome address with these words: “It is a great honour, joy and challenge to serve as ROeS president for the upcoming two years”. It is now my turn to write them and to thank you, Martin, for the great work accomplished during your tenure.

One important novelty under his governance was the formation of a Hungarian group as a new ROeS section, led by Julia Singer. This means that there are now three countries in our association. I wish a warm welcome to our Hungarian colleagues!

Of course, another major highlight of 2017 was the fantastic ROeS meeting organized by Georg Heinze and Martin Posch in Vienna as a joint conference with the German region and the ISBS. You will find a retrospective with some pictures of this event in the next few pages.

Unfortunately, the year 2017 also had its share of sad news with the passing of Klaus Abt and our former president Willi Maurer, without whom our association will not be quite the same. Two obituaries are included in this newsletter.

Let me now introduce myself. I was born in 1967 in Neuchâtel, where I got my PhD in Statistics in 1998 under the guidance of Yadolah Dodge. Nine years later, I was named Associate Professor for Biostatistics at the Institute for Social and Preventive Medicine from the University Hospital in Lausanne. In between, I spent one year as a postdoc in Canberra in the group of Peter Hall and I have worked for another 8 years as a scientific collaborator at the University of Zurich in the group headed by Theo Gasser and, later, by Leo Held, two former ROeS presidents. This is where I have learned the job of Biostatistician and developed a taste for a mixture of both theoretical and applied statistics.

Next, I would like to announce that the 2019 ROeS seminar will take place during the week **September 9–13, 2019** in Lausanne, for the first time in the French part of Switzerland. Please save the date!

The motto of the conference will be “From controlled trials to big data and back”. Ideas behind this motto are developed further in this issue. Those are of course broad ideas that will allow us to speak about (almost) any interesting topic in (bio)statistics.

Related to these considerations, there is currently a passionate debate on whether analysis of big data (e.g. based on social networks) may provide superior results than small surveys based on traditional statistics and sampling. Interestingly, the two techniques could be compared during the French presidential election in 2017. Indeed, while small but carefully done surveys rightly predicted the election of E. Macron as the new French president (and actually predicted the correct ranking of the 11 candidates, except for one inversion between candidates ranked 7 and 8, yielding a Spearman correlation of 0.99 between predicted and actual results), big data analysis wrongly predicted a success of F. Fillon (who finished third).

In France at least, traditional surveys are often so good that I used to find them undesirable. Indeed, they are discouraging “small candidates”, influencing the vote and killing the suspense. Could we imagine an election without survey? We would probably vote very differently. In particular, small candidates would probably get more votes if nobody knew they are small.

Nevertheless, my opinion has now changed. It is thanks to the daily and reliable surveys that one can study the evolution of trends, see who has some chance to win and who has not, and adapt one's vote accordingly (strategically). A tactical vote would not be possible without surveys. Repeated surveys offer much more than two rounds of voting before deciding which candidate to support and might thus represent a practical solution to the Condorcet (or voting) paradox, which states that there is no (or at least not always a) fair way to determine what is the collective preference when more than two candidates are involved. In this spirit, traditional surveys and statistics represent a precious tool for democracy.

I am looking forward to pursuing such discussions at our 2019 conference, or at another occasion this year!

Lausanne, May 2018

Valentin Rousson

CEN-ISBS Vienna 2017

Joint Conference on Biometrics & Biopharmaceutical Statistics

After Munich 2008 and Zurich 2011, the third conference of the Central European Network (CEN) was held in conjunction with the International Society for Biopharmaceutical Statistics (ISBS) at the Medical University of Vienna from August 28 to September 1, 2017. CEN consists of the German Region (IBS-DR), the Austro-Swiss Region (IBS-ROeS) and the Polish Region (IBS-PR). The more than 700 attendees were warmly received by the local organizing committee, led by Georg Heinze. The scientific programme committee was formed by the collaborating regions and societies IBS-DR, IBS-ROeS, IBS-PR and ISBS and co-chaired by Martin Posch, Vienna (IBS-ROeS), Tim Friede, Göttingen (IBS-DR), Tomasz Burzykowsky, Hasselt (IBS-PR) and Frank Bretz, Basel (ISBS). The logistic challenges in planning and organizing this joint conference of different societies, each with its own tradition, were finally mastered by a great collaboration between the scientific and local organizing committees.



After pre-conference courses on “Joint modelling of longitudinal and time to event data” (Dimitris Rizopoulos), “Bayesian pharmaceutical applications using SAS(R)” (Fang Chen, Frank Liu), “Interval-censored time to event data” (Din Chen, Tony Sun), and “Statistical evaluation of surrogate endpoints” (Tomasz Burzykowsky), the conference started with a keynote lecture by John P. A. Ioannidis on “Conceptual and statistical issues on reproducibility”, recognized by Austrian mass media. Further keynote lectures were given by Ulrich Dirnagl (“Statisticians to the rescue: a humble stroke researcher’s proposal how to improve the quality of preclinical biomedicine”), Allison Smith (“Design tableau: an aid to specifying the linear mixed model for a comparative experiment”) and Stijn Vansteelandt (“Inferring causal pathways from data: challenges and some solutions”).



The conference featured 19 further invited talks, given on invitation of the scientific programme committee, as well as 52 topic-contributed sessions and 22 contributed sessions. Particular highlights of the conference were four sessions dedicated to young statisticians, including two award sessions from the German and Austro-Swiss regions. We were also happy to provide travel support to our young academics and to researchers from lower-income countries. On the last two days, the European



Medicines Agency joined our conference by co-organizing a symposium with 9 further sessions. Several meetings of the various working groups, as well as a meeting on the “Future of CEN – interregional activities and new members”, exploring the possibilities of extending our activities beyond current limits, provided opportunities for fruitful discussions. Two further courses on “Evaluating therapies in rare diseases” and “Confirmatory adaptive designs”, and a poster (and wine) session complemented the scientific programme.



Talking about wine, also the social programme provided several highlights and reinforced possibilities for communication and networking among the 700 delegates. On Monday, some city walks were organized which featured the Ringstrasse and the famous “Palaisviertel”, a neighborhood in the inner city that boasts an unmatched wealth of private palaces. After the city tours, young researchers gathered at an informal dinner in the former General Hospital of Vienna, now partly owned by the university and by private businesses, a hot-spot of urban nightlife. Tuesday closed with a welcome reception at the magnificent Great Ball Room of Vienna’s City Hall. The traditional hiking excursion of the ROeS led through the Wienerwald (Vienna Woods), passing at the highest “summit” of Vienna, and finally ending at a traditional wine tavern. This was also the venue of the conference dinner on Thursday, which, thanks to good weather, could take place outside in a beautiful garden, accompanied by a musical performance of an uprising Viennese singer-songwriter.

A selection of photographs and the full conference programme can be found at the conference website www.cenisbs2017.org.

Georg Heinze

Protokoll der ROeS-Mitgliederversammlung 2017

Zeit: Mittwoch, 30. August 2017, 13:35-14:30

Ort: Medical University of Vienna, Lecture Hall HS3

Tagesordnung:

1. Begrüßung und Feststellung der Beschlussfähigkeit
2. Verabschiedung der Tagungsordnung
3. Bericht des Präsidenten
4. Bericht aus der IBS (Andrea Berghold)
5. Bericht der Editoren des Biometrical Journal
6. Bericht aus den ROeS Sektionen und Arbeitsgruppen
 - a. Wiener Biometrische Sektion (WBS)
 - b. Basler Biometrische Sektion (BBS)
 - c. Biometrische Sektion Steiermark-Kärnten (BSSK)
 - d. Arbeitsgruppe Adaptive und Multiple Verfahren

7. Bericht der Schatzmeisterin
8. Bericht der Kassenprüfer Hanno Ulmer und Kasper Rufibach
9. Einbindung von Sektionen aus Nachbarländern und Festlegung der anzuwendenden Mitgliedsbeiträge
10. Wahl Vorstand 2017-18
11. Wahl Beirat
12. Arthur-Linder Preis
 - a. Bekanntgabe von neuen Mitgliedern in das Komitee
 - b. Aktualisierung der Vergaberegeln (insbesondere Modus für den Ersatz von Komiteemitgliedern bei Interessenskonflikten)
13. Varia

Anmerkung: Die ROeS-Mitgliederversammlung wurde in Englisch abgehalten. Das Protokoll wurde daher ebenfalls in Englisch verfasst.

ad 1) Welcome and establishment of the quorum

Martin Posch, President of the Austro-Swiss region, welcomes the participants of the assembly. The quorum is present.

ad 2) Adoption of the agenda

The agenda is approved unanimously.

ad 3) Report of the President

Martin Posch reports on the CEN IBS conference in Vienna. The conference was organized together with Georg Heinze and was held with a balanced budget.

ad 4) Report from IBS

Andrea Berghold (Chair of Representative Council) reports about the IBS. The IBS started a journal club for members worldwide to network and discuss recent papers published in IBS journals. It is planned to hold the journal club 4 times a year. Andrea Berghold also reports about the recent activities of the Network and Inter-Regional Activities Funding Program. Additionally, Andrea Berghold informs about a system change to the process for selecting a Representative Council Chair. In order to improve continuity and communication there will be an outgoing chair (former elected chair) and an incoming chair (newly elected chair).

ad 5) Report of the editors of the Biometrical Journal

Dankmar Böhning reports about recent changes in the list of editors. The Biometrical Journal is edited in cooperation with the German and Austro-Swiss region of the IBS. The editorial board consists of 40 editors, including 2 chief editors and 1 Assistant Editor. Editors who leave the board are: Leonhard Held, Martin Schumacher, William J. Browne and Thomas Kneib.

Dankmar Böhning presents the journal statistics and trends, including impact factor trends for 2010-2016 (current impact factor: 1.075), days to first decision, the rate of manuscripts received and rejected (constant over time), and the top cited articles in 2016 (including most topics from special issues).

Dankmar Böhning announces the special issue in 2017 (Journal 2017/4) including 3 special topics: ISCB 2015, MCP 2015 and LVM long (latent variable models for longitudinal data) and call for papers for the CEN-ISBS Vienna 2017 Joint Conference Special Issue.

ad 6) Report from the ROeS sections and working groups

- a. Vienna Biometric Section of ROeS (WBS): Martin Posch reports that a series of colloquia and seminars have been held over the last two years. A detailed list of the colloquia and seminars can be found on the homepage www.meduniwien.ac.at/wbs/.
- b. Basel Biometric Section of ROeS (BBS): Ulrich Burger reports about several half day events and 4-6 seminars which were well attended. A detailed list can be found on the homepage at www.ceb-institute.org/bbs/.
- c. Styria-Carinthia Biometric Section of ROeS (BSSK): Andrea Berghold reports that a symposium was held in Graz in 2017 together with the WBS for the purpose of scientific exchange. It is planned to hold these seminars at regular intervals.
- d. Adaptive Designs and Multiple Testing Procedures: Martin Posch reports on the recently held workshop in Cambridge, which was very well attended by more than 60 participants. The workshop in 2016 was also held with a good number of participants.

ad 7) Report of the Treasurer

Shu-Fang Hsu Schmitz reports on ROeS finances and presents the financial statements for the years 2015-2016. In Austria, revenues from the conference in 2015 amounted to approximately 17.503 euros. The total expenditure amounts to approximately 15.021 euros. In summary, a profit was recorded in Austria and a small loss was recorded in Switzerland. The detailed financial statements for 2015-2016 are attached.

ad 8) Report of the cash auditors

Hanno Ulmer reports that the accounts are being kept in an exemplary manner and requests that the actions of the board of directors be ratified.

ad 9) Involvement of sections from neighboring countries and determination of the applicable membership fees

Martin Posch reports that he was approached by Julia Singer (president of the Hungarian Society for Clinical Biostatistics) regarding the formation of a Hungarian group of the IBS. It is proposed that the Hungarian group (at the moment: consisting of about 10 full members) becomes a section within the ROeS. The inclusion of the new ROeS section will not change the name of the society.

For the ROeS membership, the Hungarian group requests a reduced membership fee. It is proposed that the membership fee for a regular member in Hungary (including online access to JABES, Biometrics, and Biometrical Journal) is reduced to 30 euro for the next 4 years. For the other membership categories (Senior retiree member, Student member) the fee will be unchanged. Shu-Fang Hsu Schmitz confirms that this is financial possible.

The proposals were well received in the meeting. In the meeting, the admission of Hungary as a new ROeS section and the reduced membership fees were voted on. **The vote was unanimously positive.**

ad 10) Election of the ROeS Board 2017-2018

Valentin Rousson is running for president and is elected unanimously. Valentin Rousson introduces himself briefly and discusses the next ROeS Conference 2019, which will take place in Lausanne.

Shu-Fang Hsu Schmitz is available as treasurer and is re-elected unanimously. Regina Riedl is available as secretary and is re-elected unanimously. Michael Vock continues to be responsible for ROeS news.

ad 11) Election of the Advisory Board

The ROeS Board proposes that Arne Bathke, Georg Heinze and Franz König from Austria be elected to the Advisory Board. Dominik Heinzmann and Simon Wandel from Switzerland are proposed. The vote was unanimously positive.

ad 12) Arthur-Linder Prize

This year's Arthur Linder Prize was awarded to Robin Ristl, Heidi Seibold and Susanne Urach.

- a. Announcement of new members to the Committee: Sereina Herzog (Austria) and Dominik Heinzmann (Switzerland) are available for the new jury of the Arthur Linder Prize and are elected unanimously.
- b. Updating the award rules: To prepare for situations where there is a conflict of interest and to provide a better option to adapt the number or kind of awards given, the ROeS board proposes a change of the Arthur Linder Prize award rules documented in the Annex. The following changes or additions to the Arthur-Linder Prize award rules are proposed:
 - Ad 3. *„Die zweijährliche Preissumme beträgt Sfr. 2000.- und kann jederzeit neu festgelegt werden. Sie kann auf höchstens zwei Preisträger aufgeteilt werden.“* the following modification is proposed:
*„Die zweijährliche Preissumme beträgt Sfr. **3000.-** und kann jederzeit neu festgelegt werden. Sie **soll** auf höchstens zwei Preisträger aufgeteilt werden.“*
 - Ad 5. As a mode for replacing jury members in the event of conflicts of interest, the following addition is proposed:
„(...) Nach Sichtung der Einreichungen haben die Jurymitglieder zu prüfen, ob eine Befangenheit aufgrund eines Naheverhältnisses zu den antragstellenden Personen vorliegt. Ist eines oder mehrere Jurymitglieder befangen, so scheiden diese aus der Jury aus und der Vorstand der ROeS wählt Ersatzmitglieder.“

At the assembly, these changes were unanimously approved.

ad 13) Varia

Andrea Berghold announces the event: “19. Jahrestagung des Deutschen Netzwerks Evidenzbasierte Medizin (DNEbM)” which will be held at the Medical University of Graz in 2018 (<http://www.ebm-kongress.de/>).

Regina Riedl

Anhang: Zweijahresrechnung 2015 + 2016

A. OESTERREICH

| <u>Einnahmen:</u> | <u>Euro</u> |
|--|-------------|
| Mitgliederbeiträge | 7'820.00 |
| Zinsertrag | 00.03 |
| Einnahmen Tagung 2015 / Details in AUT | 17'503.64 |
| | 25'323.67 |

| <u>Ausgaben:</u> | <u>Euro</u> |
|--|-------------|
| Kosten Tagung 2015 Milano | 7'994.10 |
| Wiley, Biom. Journal 2016 | 1'998.75 |
| Bankspesen, Gebühren, Porti | 836.91 |
| div. Kosten Homepage | 870.00 |
| Arthur-Linder-Preis Hlavin Gerald | 2'000.00 |
| BA für Erwachsenenbildung; Sponsoring | 999.50 |
| Landespolizei, Statutenänderung | 22.10 |
| Dozententätigkeit Sommerschule, Rauch G. | 300.00 |
| | 15'021.36 |

| | |
|-------------------------|-----------------------|
| Einnahmen überschuss | <u>Euro 10'302.31</u> |
|-------------------------|-----------------------|

B. SCHWEIZ

| <u>Einnahmen:</u> | <u>sFr.</u> |
|-----------------------------|-------------|
| Mitgliederbeiträge | 9'733.00 |
| E-Payment Rückerst. / Korr. | 292.14 |
| Zinsertrag | 14.83 |
| Übertrag CS-Sparkonto | 9'453.03 |
| | 19'493.00 |

| <u>Ausgaben:</u> | <u>sFr.</u> |
|---|-------------|
| div. Frankaturen | 578.00 |
| IBS, Payment Dues Renewal 2015 + 2016 | 15'063.82 |
| Druckkosten ROeS Newsletter | 136.30 |
| E-Payment Belastungen / Details in AUT | 842.94 |
| Donation Conference 2015 / USD 1'000.00 | 980.50 |
| Bankspesen, Gebühren, Porti | 58.55 |
| Neugestaltung Webseite | 1'736.10 |
| Wiley, Biom. Journal 2015 | 2'197.40 |
| Reisespesen Tagung 2015 Milano | 1'506.14 |
| Seibold / Salär, Tagung 2015 Milano | 6'730.00 |
| Saldierung CS-Sparkonto | 9'453.03 |
| | 39'282.78 |

| | |
|--------------------|-----------------------|
| Ausgabenüberschuss | <u>sFr. 19'789.78</u> |
|--------------------|-----------------------|

| <u>Vermögensnachweis</u> | <u>1.1.2015</u> | <u>31.12.2016</u> |
|--------------------------|-----------------|-------------------|
| Creditanst./Bank Austria | 11'949.21 | 22'251.52 |
| | 11'949.21 | 22'251.52 |

| <u>Vermögensnachweis</u> | <u>1.1.2015</u> | <u>31.12.2016</u> |
|--------------------------|-----------------|-------------------|
| PC-Konto 80-62648 | 31'454.51 | 11'675.75 |
| CS, Bern PK 169586-60 | 9'476.53 | 0.00 |
| CS, Bern PK 169586-60-1 | 41'011.30 | 50'476.81 |
| | 81'942.34 | 62'152.56 |

| | |
|---------------------|-------------------------|
| Vorschlag 2015-2016 | <u>+ 10'302.31 Euro</u> |
|---------------------|-------------------------|

| | |
|---------------------|-------------------------|
| Vorschlag 2015-2016 | <u>- 19'789.78 sFr.</u> |
|---------------------|-------------------------|

New members of the ROeS Advisory Board

Simon Wandel was born in 1983 in Bern, Switzerland. He holds a master in Statistics and a PhD in Medical Statistics/Epidemiology (both from University of Bern). In 2010, he joined the Early Clinical Biostatistics Group at Novartis Oncology as statistician, where he had roles with increasing responsibility. In 2013, he co-founded a start-up specialized for Bayesian statistics (Cogitars GmbH), before he joined Novartis Oncology's Statistical Methodology Group in late 2014. In this role, he provided statistical expertise for all phases of development, with a specific focus on adaptive Bayesian phase I/II studies. In 2017, he became a member of Novartis' Statistical Methodology and Consulting group, providing methodological support for various disease areas.

Simon Wandel has a particular interest in application of Bayesian statistics for clinical trials and evidence synthesis. He has worked as responsible or consulting statistician for more than 30 fully Bayesian phase I/II trials, which included extensive work with other statisticians, clinicians, approval boards and regulatory agencies. Recently, he also gained experience in phase III, including submission and related statistical challenges.

Simon is actively engaged in several collaborations between academia and industry, and other groups such as the Basel Biometric Section and the EFSPI.

Georg Heinze is head of the Section for Clinical Biometrics at CeMSIIS, Medical University of Vienna. He received a PhD degree in Statistics from the University of Vienna in 1998 and is Associate Professor at the Medical University of Vienna since 2004. He served as chairman of the local organizing committee of the CEN-ISBS Vienna 2017, as chairman of the scientific programme committee of the ISCB Vienna 2014, and as president of the Vienna Biometric Section from 2010-2012.

His primary research focuses on biostatistical regression modeling strategies for and estimation of effects of exposures on outcomes, particularly when sample sizes are small or outcome events are rare. His secondary research focus is the re-use of health data for medical research, particularly when sample sizes are very large, as in nationwide studies on health insurance claims. He has collaborated as biostatistical partner in several EU-funded projects. He currently supervises four PhD students and two PostDoc researchers.

Arthur-Linder-Preis

Mit dem Arthur-Linder-Preis fördert die Region Österreich-Schweiz der Internationalen Biometrischen Gesellschaft den wissenschaftlichen Nachwuchs. In Ehrung von Arthur Linder wird dieser Preis alle zwei Jahre für Forschungsarbeiten im Gebiet der Biometrie verliehen. Bei der Joint Conference on Biometrics & Biopharmaceutical Statistics (CEN-ISBS) 2017 wurden Robin Ristl, Heidi Seibold und Susanne Urach ausgezeichnet. Die Jury bestand aus Dr. Hans Ulrich Burger mit dem externen Reviewer Prof. Ulrich Mansmann. Sie entschied sich für folgende Preisträger und deren Arbeiten:

Robin Ristl

Im Artikel „Optimal exact tests for multiple binary endpoints“ (<https://doi.org/10.1016/j.csda.2018.01.001>) entwickelte Robin Ristl zusammen mit den Koautoren Xi Dong, Ekkehard Glimm und Martin Posch statistische Tests zum Vergleich von zwei Behand-

lungen anhand mehrerer binärer Endpunkte. Diese finden in medizinischen Studien Anwendung, in denen die Wirksamkeit einer experimentellen Behandlung durch mehrere binäre Erfolgskriterien gemessen wird. Die Verfahren, die in der prämierten Arbeit „Optimal exact tests for multiple binary endpoints“ beschrieben wurden, erfüllen verschiedene Optimalitätskriterien, um die Wahrscheinlichkeit, einen Behandlungseffekt nachzuweisen, zu maximieren. Gleichzeitig wird gewährleistet, dass die Wahrscheinlichkeit für falsch positive Ergebnisse einen festgelegten Wert nicht überschreitet. Die Konstruktion dieser multivariaten, verallgemeinerten Fisher's Exact Tests erfolgt durch Methoden der numerischen Optimierung. Insbesondere für Studien mit geringer Fallzahl, wie sie in der Erforschung von Therapien seltener Erkrankungen eingesetzt werden, stellen die resultierenden optimalen exakten Tests einen deutlichen Fortschritt im Vergleich zu bestehenden Verfahren dar.

Zur Person: Robin Ristl studierte an der Universität für Bodenkultur in Wien Lebensmittel- und Biotechnologie und promovierte 2012 mit einer Arbeit über bakterielle Proteinglykosylierung. Parallel dazu studierte er Statistik an der Universität Wien, wo er 2013 das Bakkalaureatsstudium und 2016 das Masterstudium abschloss. Er ist derzeit Universitätsassistent am Institut für Medizinische Statistik, Zentrum für Medizinische Statistik, Informatik, und Intelligente Systeme (CeMSIIS) der Medizinischen Universität Wien.

Heidi Seibold

Im Artikel „Individual treatment effect prediction for amyotrophic lateral sclerosis patients“ (<https://doi.org/10.1177/0962280217693034>) – erschienen in *Statistical Methods in Medical Research* – beschreiben Heidi Seibold, Achim Zeileis und Torsten Hothorn, wie modellbasierte Zufallswälder genutzt werden können, um Patientencharakteristika zu identifizieren, die einen Einfluss auf den Behandlungseffekt haben, und um personalisierte Behandlungseffekte zu schätzen. Die Methode baut auf klassische Modelle zur Schätzung von Behandlungseffekten, wodurch sie für Anwender leicht verständlich ist. Die Kommunikation der Ergebnisse kann durch einfache Visualisierungen unterstützt werden. Die Anwendung der neuen Methode auf der Datenbank „PRO-ACT“ zeigt, dass der Behandlungseffekt von Riluzole bei Patienten mit Amyotropher Lateralsklerose (ALS) heterogen ist und die Visualisierung der personalisierten Modelle gibt einen Einblick in den Einfluss der Patientencharakteristika auf den Effekt von Riluzole.

Zur Person: Heidi Seibold studierte bis 2014 an der LMU München Statistik und promovierte zum Zeitpunkt der Preisverleihung an der Universität Zürich im strukturierten Promotionsprogramm „Epidemiology and Biostatistics“. Ihre Dissertation hat den Titel „Model-Based Recursive Partitioning for Stratified and Personalised Medicine“ und wurde von Torsten Hothorn betreut. Im März 2018 verteidigte sie ihre Doktorarbeit und arbeitet mittlerweile am Institut für Medizinische Informationsverarbeitung, Biometrie und Epidemiologie (IBE) in München.

Susanne Urach

Im prämierten Artikel „Multi-arm Group Sequential Designs with a Simultaneous Stopping Rule“ in *Statistics in Medicine* (S. Urach und M. Posch, <https://doi.org/10.1002/sim.7077>) wurden statistische Testverfahren für mehrarmige Therapiestudien mit Zwischenanalysen untersucht. Ein wichtiger Faktor dabei sind die Stoppregeln, die angeben, unter welchen Voraussetzungen eine Studie bereits in einer Interimsanalyse gestoppt werden kann. Im Rahmen der Arbeit wurden Testprozeduren entwickelt, die für die gewählte Stoppregel optimiert sind. Insbesondere für die sogenannte „simultane Stoppregel“, für die eine Studie

in einer Zwischenanalyse beendet wird, wenn für mindestens einen der Studienarme ein Behandlungseffekt nachgewiesen werden kann, wurde eine neuartige, effizientere Testprozedur entwickelt. Diese erreicht ohne Erhöhung der Fallzahl eine höhere statistische Power als herkömmliche Verfahren.

Zur Person: Susanne Urach schloss 2010 das Diplomstudium Physik, 2012 das Lehramtsstudium Physik/Mathematik und 2013 das Bachelorstudium Mathematik an der Universität Wien ab. Seit November 2013 ist sie wissenschaftliche Mitarbeiterin am Institut für Medizinische Statistik, Zentrum für Medizinische Statistik, Informatik, und Intelligente Systeme (CeMSIIS) der Medizinischen Universität Wien und schloss dort im Juni 2018 ihr PhD-Studium mit einer Dissertation zu „Clinical trials with multiple objectives in small populations“ (Betreuer: Martin Posch) ab.

Nachrufe / Obituaries

Klaus Abt, 1927–2017

Prof. Dr. Klaus Abt (geb. 1927) ist im April 2017 nach langer schwerer Krankheit verstorben. Prof. Abt begann seine wissenschaftliche Tätigkeit in der angewandten Statistik an der Universität Genf. Er promovierte bei Prof. Arthur Linder und übernahm auch Lehraufgaben an der ETH Zürich. Nach einer Auslandstätigkeit in Dahlgren/Virginia, USA, von 1959 bis 1967, arbeitete er nach seiner Rückkehr nach Europa zunächst bei der Firma Sandoz in Basel. Im Jahr 1973 nahm er einen Ruf auf eine Professur an den Fachbereich Medizin der Goethe-Universität Frankfurt an und leitete die „Abteilung Biomathematik“ bis zu seiner Emeritierung im Jahr 1993.

Seine wissenschaftliche Schwerpunkte lagen seit Beginn in der unbalancierten Varianz- und Kovarianzanalyse und ganz allgemein in Methoden der Computer-orientierten angewandten Biostatistik.

Bereits seit den 60er Jahren war Prof. Abt aktives Mitglied der Internationalen Biometrischen Gesellschaft und Mitglied der ROeS sowie seit 1973 auch der Deutschen Region (DR). Er engagierte sich insbesondere im Beirat der DR und in der AG „Didaktik der Biometrie“, die er 1993 mit Rolf Lorenz begründete und deren Vorsitz er bis 1997 inne hatte. Insgesamt nahm er regelmäßig an Seminaren der ROeS und den Biometrischen Kolloquien der Biometrischen Gesellschaft teil.

Seine Kollegen und Mitarbeiter haben seine pragmatische Art, seine didaktischen Fähigkeiten und seine menschlichen Qualitäten sehr geschätzt. In der Sache war er „unerbittlich“, aber immer verbindlich, entgegenkommend und hilfsbereit.

Eva Herrmann und Hanns Ackermann

Willi Maurer, 1941–2017

It is with great sadness that we share with you that Willi passed away on December 30 after a long illness.

Willi joined Sandoz in 1978 and served as Global Head of Biostatistics at Novartis after the merger in 1996. Shortly afterwards, he founded the Statistical Methodology group which he led up to his retirement in 2006. Since then he continued actively working as a prime force consultant for Novartis until a few months ago.

It is difficult to find the right words to describe Willi as he was truly an outstanding person, someone filled with love, kindness, sincerity, and modesty. Willi was a role model to everyone who was fortunate to have been mentored by and exposed to him. He led by example as he openly listened to new ideas and encouraged others to speak up, especially his younger colleagues. He had a tremendous impact on drug development throughout his career.

As such, Willi was a respected thought leader within industry, academia, and the regulatory community who influenced the careful and responsible implementation of innovative trial designs and new statistical methodology at all stages of drug development. In particular his groundbreaking work on multiplicity and adaptive designs has fundamentally changed the clinical trial landscape.

Willi was also a very active member in the Basel Biometric Section (BBS) as well as in the Austro-Swiss Region (ROeS) of the International Biometric Society (IBS). Being a ROeS member since 1977, he was the president 2002–2003 and organized a wonderful ROeS seminar in his home town, St. Gallen. Even after his presidency he stayed engaged and was the local organizer of the ROeS seminar 2007 in Bern and a key member of the organizing committee for the first Central European Network (CEN) conference led by ROeS in Zurich 2011. His humbleness, insights and pragmatism were essential for the success of these seminars, and last but not least it was always a pleasure working with him on such events.

All these contributions to the profession and to drug development made him a leading figure of our society, recognized in 2015 by the ROeS who bestowed on Willi the honor of becoming one of its Honorary Life Members.

We are very sad to lose Willi but we certainly are so grateful to have been his work colleagues and friends and we can all treasure the moments and interactions we had with such an esteemed person. Like so many of us, Willi was passionate about his work and devoted his professional life to drug development. Willi personified our drive to deliver medicines that can make a difference for patients, and he continued to do so when he became a patient himself. His career and the legacy he leaves is an inspiration to all of us.

Frank Bretz, Amy Racine and Uli Burger

Aus den Sektionen und der Arbeitsgruppe

Wiener Biometrische Sektion

Das vergangene Jahr war – sowohl hinsichtlich Vorträgen im „Biometrischen Kolloquium“ als auch Seminaren – ein sehr aktives Jahr. Die Seminare beinhalteten einen Kurs „Exploratory Subgroup Analyses in Clinical Trials“, eine Seminarreihe der „Young Statisticians“ im Rahmen des EU Projektes IDEAS, sowie ein „Biosimilar Forum“, das gemeinsam mit der Ungarischen Gesellschaft für Klinische Biostatistik organisiert wurde. Die gemeinsamen Aktivitäten mit der Biometrischen Sektion Steiermark-Kärnten (in diesem Jahr findet das gemeinsame Seminar im Herbst in Wien statt), sowie der Ungarischen Gesellschaft für Klinische Biostatistik (das „Biosimilar Forum“ findet am 25./26. Oktober dieses Jahres zum dritten Mal statt) werden weiter fortgesetzt. In diesem Jahr fand auch bereits eine Reihe von Vorträgen statt und ein Workshop mit Sonja Swanson zum Thema „Instrumental Variable Methods in Epidemiology“. Eine detaillierte

Auflistung sämtlicher Aktivitäten ist auf der Homepage www.meduniwien.ac.at/wbs/ zu finden. Im Juni wurden Harald Herkner und Susanne Strohmaier (beide forschen an der Medizinischen Universität Wien) einstimmig zum neuen Vorstand für die nächsten beiden Jahre gewählt.

Stephan Lehr

Arbeitsgruppe „Adaptive Designs and Multiple Testing Procedures“ (gemeinsame Arbeitsgruppe mit der IBS-DR)

Der Workshop 2017 der AG Adaptive Designs and Multiple Testing Procedures fand am 8. und 9. Juni 2017 in Cambridge (England) mit über 60 Teilnehmern statt. Der Workshop wurde diesmal in Zusammenarbeit mit dem „Hub for Trials Methodology Research Adaptive Designs Working Group“ des britischen Medical Research Council veranstaltet. Das wissenschaftliche Programm bestand aus 34 Vorträgen und wurde etwa zu gleichen Teilen von Mitgliedern der Arbeitsgruppe und britischen Kollegen bestritten.

Am 31. März 2017 wurde die „Draft guideline on multiplicity issues in clinical trials“ der European Medical Agency (EMA) zur Kommentierung freigegeben. Die Arbeitsgruppe hat hierfür Kommentare aus Ihrem Mitgliederkreis gesammelt und eingebracht. Die Kommentare sind auch auf der Webseite der Deutschen Region der IBS zur Nachlese veröffentlicht (<http://www.biometrische-gesellschaft.de/publikationen/stellungnahmen/ema.html>).

Von der AG Adaptive Designs and Multiple Testing Procedures wurde auf der CEN-ISBS Vienna 2017 die Topic-Contributed Session „Adaptive designs and multiple testing procedures for small populations“ organisiert. Hier wurden neue Ansätze des multiplen Testens und einer flexiblen Studienführung im Kontext von Studien mit kleinen (z.B. biomarker-stratifizierten) Studienpopulationen vorgestellt und diskutiert.

Der nächste Workshop der Arbeitsgruppe wird am 4. und 5. Oktober 2018 an der Universität Bremen (Deutschland) stattfinden. Die Anmeldung ist über die Webseite des Workshops (<http://admp.uni-bremen.de/>) möglich. Im Rahmen des Workshops wird es auch eine Ehrensession im Gedenken an Willi Maurer geben – Peter Bauer, Gerhard Hommel, Frank Bretz und Ekkehard Glimm haben als Redner bereits zugesagt.

Des Weiteren ist die AG auch schon in Vorbereitungen zur DAGStat-Tagung 2019 in München (18.–22.03.2019) involviert. Hier organisiert der stellvertretende Sprecher gemeinsam mit Prof. Dr. Rainer Schwabe (Leipzig) eine Sektion zum Thema „Design of Experiments and Clinical Trials“.

Florian Klinglmüller

Veranstaltungshinweise / Events

Adaptive Designs and Multiple Testing Procedures – Annual Workshop

Bremen, October 4–5, 2018

<https://admp.uni-bremen.de/>

Gemeinsames Seminar der Wiener Biometrischen Sektion und der Biometrischen Sektion Steiermark-Kärnten

Wien, 29. November 2018, 10:30-16:15

**XXXIst Conference of the Austro-Swiss Region (ROeS)
of the International Biometric Society
From Controlled Trials to Big Data and Back**

Lausanne, September 9–13, 2019

Statistical data analyses are sometimes classified as being either of an exploratory or of a confirmatory nature, while the reality of most statistical practice often lies somewhere in between. This middle territory is perfectly exemplified by the problem of “model selection” and Frank Harrell’s famous words: “Using the data to guide the data analysis is almost as dangerous as not doing so”.

The most accomplished confirmatory statistical analyses are conducted in the context of controlled (clinical) trials, where regulations and guidelines are in place to ensure that every single step of a statistical analysis is fully protocolled and planned. On the other hand, we are now living in the era of “big data” and “data science”, where extreme forms of exploratory data analyses are encouraged, and data quantity prevails over data quality. Classical concerns such as data representativeness, data reliability, overfitting and reproducibility are not always sufficiently considered in the big data world where there is the belief that any kind of data may contain precious information capable of answering questions that have yet to be imagined.

While assessing the achievements of the big data approach is another challenging statistical question, there is currently some perception that “those who ignore statistics are condemned to reinvent it”, as Brad Efron once said. In particular, it might ultimately be recognized that one cannot simply replace the subtle concepts of statistical inference developed by statisticians over decades with nice graphics. Sooner or later, it will be time to come back from the big data paradigm towards more classical approaches and concerns and to land somewhere between the two extremes of the purely confirmatory and purely exploratory data analyses.

The XXXIst ROeS statistical conference, which will gather and devote sessions to clinical trialists, theoretical and applied (bio)statisticians (to real life data in the domains of medicine, biology, genetics, agriculture, among others), data scientists and big data analysts, will be a timely occasion to try to define what this “middle ground” should or could be to best meet the expectations of scientists.

XXX International Biometric Conference (IBC 2020)

Seoul, Korea, July 5–10, 2020

Joint Meeting of the Central European Network of the IBS and the GMDS

Berlin, September 6–11, 2020

Save the date: From September 6–11, 2020 the Central European Network of the IBS will hold a joint meeting with the GMDS at the Charité in Berlin.

XXXI International Biometric Conference (IBC 2022)

Riga, Latvia, July 2022