

Referat

Møde : Generalforsamling
 Mødested : Kosmopol, Fiolstræde 44, Copenhagen
 Dato : Torsdag d 9. maj 2019 kl 16:00
 Deltagere : Bestyrelsen + fremmødte medlemmer
 Referent: Mette Krog Josiassen

Dagsorden

1. Valg af dirigent
2. Formandens beretning
3. Fremlæggelse og godkendelse af regnskab
4. Fremlæggelse af aktivitetsplan og budget
5. Fastlæggelse af kontingent
6. Valg af bestyrelsesmedlem og revisor
7. Fremsatte forslag
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1. Valg af dirigent

Lars Holm Damgaard blev valgt som dirigent.

2. Formandens beretning

Bestyrelsens medlemmer har i år været Henrik Ravn (webansvarlig), Mette Krog Josiassen (Sekretær og EFSPI repræsentant), Rebecca Zachariae Nielsen (på barsel), Gabriela Martinez Ravn (Kasserer), Birgitte Rønn (EPSPI repræsentant og Formand). Derudover har vi suppleanterne Anita Meldgaard, Ólöf Thórisdóttir (på barsel) og Søren Tamer.

Foreningen har i 2018/2019 stort set holdt sin størrelse idet vi er gået fra 206 til 208 medlemmer.

I løbet af det sidste år har vi haft arrangementer af forskellig karakter:

Sidste år havde vi generalforsamling 19/4 2018, på Kosmopol. I den forbindelse var et faglig arrangement, med foredrag om "Mediation Analysis - with an example" ved Klaus Groes Larsen, Lundbeck A/S og "Estimands - Interpreted by China, EMA and FDA, an example from the Ozempic® label" ved Trine Saugstrup & Lars Holm Damgaard, Novo Nordisk A/S. Det faglige møde var velbesøgt med 41 deltagere og en stor del blev til den efterfølgende generalforsamling og middag.

Den 23 oktober 2018 havde vi det bi-årige fælles møde med den svenske forening, FMS. I år blev mødet holdt i Danmark på Restaurant Kastrup Strandpark, med et overordnet emne omkring Kausalitet. Der var foredrag af Arvid Sjölander, Karolinska, Sverige (Introduction to the field of causal inference), Björn Bornkamp, Novartis, Schweiz (Causal inference with a clinical trial perspective) David Svensson, AZ, Sverige (To what extent do biomarker subgroup detection

algorithms to rank prognostic variables instead of predictive ones? A simulation comparison of SIDES and Virtual Twin), Christian Bressen Pipper, Leo Pharma, Danmark (Testing treatment equivalence in a survival setting), Philip Hougaard, Lundbeck, Denmark (Assessment of a treatment effect for recurrent event data in the presence of a terminal event) and Bénédicte Delcoigne, Karolinska, Sverige (Federated analyses: technical, statistical and human challenges) og pga et afbud på dagen, præsenterede Martin Linder, Novo Nordisk, Danmark, mediations analyser fra LEADER studiet. Mødet var velbesøgt med 79 deltagere, på trods af lidt sen annoncering og planlægning.

Den 14 november 2018 blev holdt et halvdags arrangement hos Lundbeck a/s "DSBS meeting on Extrapolation in paediatrics and use of external data in pivotal clinical trials", hvor der var foredrag af Franz König (Beyond RCTs - using historical data in pivotal clinical trials) og (Adaptive paediatric investigation plans). Her benyttede vi os af lejligheden, hvor Franz alligevel var i København, til at få ham til at tale i DSBS regi også. Vi vil gerne opfordre medlemmer til at henvende sig hos os, hvis de på lignende vis bliver opmærksomme på gæster i området som kunne være relevante som foredragsholdere for DSBS, således at vi kan forsøge at invitere til og planlægge den slags events

Den 27 november 2018 blev holdt et introduktions kursus til R på Novo Nordisk a/s. Dette kursus er fulgt op af to halvdags arrangementer: Et om R og overlevels analyse på Leo Pharma, og et om R og Markdown & Tidyverse på Novo Nordisk.

Vi har vurderet at der blandt vore medlemmer er interesse for at have disse halvdags events om R indenfor specielle statistiske discipliner, så det regner vi med at fortsætte med at planlægge også de kommende år. Foreløbigt har vi planlagt to kommende events omkring R og multiplicitet samt R og shiny apps.

I januar/februar 2019 blev tredje runde af kurset 'Survival Analysis in Clinical Trials' afholdt. Per Kragh Andersen, KU og Henrik Ravn, Novo Nordisk, var igen undervisere på kurset. Der var plads til 35 deltagere, og kurset blev ikke fuldt booket, denne gang. Igen, var deltagerne meget tilfredse med kurset. Vi tænker at der ikke er publikum til en runde 4 i 2020, men måske i 2021.

Bestyrelsen vil gerne takke vore firma medlemmer for at støtte vores aktiviteter med lokaler og catering og vi håber at vi fortsat kan trække på Jeres velvilje og gæstfrihed.

Derudover er DSBS afhængig af at medlemmerne vil bidrage med faglige indlæg ved vore møder og vi er glade for at se at der fortsat er mange som har lyst til at deltage i vore arrangementer.

Brexit har ramt EFSPI. EFSPI har fået etableret sig som organisation i Danmark, hvilket har krævet at der er en Dansk direktør. Dette er en post, som vi tænker skal være besat med et medlem fra eller en repræsentant for DSBSes bestyrelse – den første er blevet Mette Krog Josiassen. For at sikre at ingen kommer til at hæfte personligt på noget tidspunkt har EFSPI købt en bestyrelses forsikring, således at hele EFSPI council nu er dækket.

I 2020/21 har vi, udover de nævnte halvdags møder om R, planer om at afholde to kurser og to fælles arrangement med DSTS: Til september kommer et kursus om adaptive design med Christopher Jennison, og til Februar 2020 et kursus om kausal analyse med Arvid Sjölander. Med DSTS planlægger vi et gå-hjem-agtigt møde omkring grafisk præsentation af data samt evt to-dags

mødet i efteråret (DTU) omkring big data/AI.

Derudover vil vi gerne have genoptaget traditionen med DSBS kommentering af guidelines/points to consider fra myndighederne, så hvis nogle medlemmer bliver opmærksomme på relevante sådanne der er kommet i review, må de meget gerne tage kontakt til bestyrelsen så vi kan planlægge et diskussionsmøde og koordinere kommentarer i den forbindelse.

Foreningens hjemmeside, har igennem mange år været placeret hos et webhotel, der nu med udgangen af juni, har besluttet at stoppe med yde denne service. Vi er derfor nødt til at finde et andet sted at have vores hjemmeside. I samme forbindelse har vi besluttet at få opdateret hjemmesiden – ikke fordi vi utilfredse men udtrykket – snarere fordi vi må erkende at der i bestyrelsen er begrænset kompetence og interesse for at programmere HTML. Vi er derfor interesserede i en løsning, der gør det let for den til en hver tid udpegede webmaster, at uploade indhold og lave andre modifikationer af siden. Hvis der er medlemmer, som har erfaring og interesse for hvordan den slags løsninger implementeres, så hører Henrik meget gerne fra jer – for eksempel i dag - da opgaven er ret akut.

Et sidste emne jeg vil tage op, er vores kontingent: Som vedtægterne er nu kan man blive medlem, hvis det firma man arbejder for er medlem, eller hvis bestyrelsen tildeler en individuelt medlemskab. Kontingentet for firma medlemskab er 3000 kr/år hvor udover man skal betale individuelt medlemskab på 150 kr/år. Vi har i bestyrelsen igennem flere år drøftet at dette skaber stor ulighed blandt den medlemskare vi har, idet vi har nogle få, relativt store medlemsfirmaer og en del meget små medlemsfirmaer. For et en mands eller tomands firma fylder firmamedlemskabet relativt meget, mens det for de større firmaer betyder relativt lidt. Samtidigt har DSBS igennem flere år akkumuleret lige rigeligt mange aktiver – i år kommer vi således også ud med et overskud, på trods af vores forsøg på at undgå dette. Derfor vil bestyrelsen gerne foreslå generalforsamlingen at ændre firmakontingentet til 50 kr/år og det individuelle medlemskab til 175 kr/år og have en afstemning herom. Gabriela Ravn vil komme nærmere ind på de økonomiske konsekvenser af dette i forbindelse med gennemgangen af regnskab og budget og vi vil have afstemningen under dette punkt.

Til sidst vil jeg igen opfordre medlemmerne til at komme med ideer og forslag til emner der skal behandles, foredrag der bør holdes og kurser vi kan udbyde.

3. Fremlæggelse og godkendelse af regnskab

Regnskabet blev fremlagt og godkendt.

4. Fremlæggelse af aktivitetsplan og budget

Aktivitetsplan og budget for næste år blev fremlagt både med og uden den foreslåede ændring til kontingent. Generalforsamlingen tilsluttede sig bestyrelsens forslag om at ændre kontingentet og budgettet blev godkendt.

5. Fastlæggelse af kontingent

Kontingentet besluttet ændret (50 DKK for firmamedlemskab, 175 DKK for personligt medlemskab).

<p>6. Valg af bestyrelsesmedlem og revisor</p> <p>a) Rebecca Zachariae Nielsen (LEO Pharma) har siddet i bestyrelsen i én periode, og bestyrelsen foreslog at Rebecca genvælges. Rebecca blev genvalgt.</p> <p>b) Som revisor har bestyrelsen foreslået Henrik Wachman, Larix. Henrik blev genvalgt.</p> <p>c) Ingen forslag fra medlemmer til kandidater til bestyrelse og revision var indkommet.</p>
<p>7. Fremsatte forslag</p> <p>Ingen indkomne forslag</p>
<p>8. Eventuelt</p> <p>Ingen indkomne forslag</p>

12 DEC 2019 

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Chairman's report

The members of the Board have this year been Henrik Ravn (webmaster), Mette Krog Josiassen (Secretary and EFSPI representative), Rebecca Zachariae Nielsen (on maternity leave), Gabriela Martinez Ravn (Treasurer), Birgitte Rønn (EPSPI representative and Chairman). In addition, we have the substitutes Anita Meldgaard, Ólöf Thórisdóttir (on maternity leave) and Søren Tamer.

In 2018/2019, the association has largely kept its size as we have gone from 206 to 208 members.

During the last year we have had events of different character:

Last year we had a general meeting on 19/4 2018, at Kosmopol. In this connection, a scientific event, with presentations on "Mediation Analysis - with an example" by Klaus Groes Larsen, Lundbeck A / S and "Estimands - Interpreted by China, EMA and FDA, an example from the Ozempic® label" by Trine Saugstrup & Lars Holm Damgaard, Novo Nordisk A / S. The scientific meeting was well attended with 41 participants and a large part was for the subsequent general meeting and dinner.

On October 23, 2018, we had the bi-annual joint meeting with the Swedish association, FMS. This year, the meeting was held in Denmark at Restaurant Kastrup Strandpark, with an overall topic about causality. There was lecture by Arvid Sjölander, Karolinska, Sweden (Introduction to the field of causal inference), Björn Bornkamp, Novartis, Switzerland (Causal Inference with a clinical trial perspective) David Svensson, AZ, Sweden (To what extent do biomarker subgroup detection algorithms top prognostic variables instead of predictive ones? simulation comparison of SIDES and Virtual Twin), Christian Bressen Pipper, Leo Pharma, Denmark (Testing treatment equivalence in a survival setting), Philip Hougaard, Lundbeck, Denmark (Assessment of a treatment effect for recurrent event data in the presence of a terminal event) and Bénédicte Delcoigne, Karolinska, Sweden (Federated analyzes: technical, statistical and human challenges) and due to a very late cancellation, Martin Linder, Novo Nordisk, Denmark, presented mediation analyzes from the LEADER study. The meeting was well attended with 79 participants, despite some late advertising and planning.

On November 14, 2018, a half-day event was held at Lundbeck a/s: "DSBS meeting on extrapolation in pediatrics and use of external data in pivotal clinical trials", where Franz König (Beyond RCTs - using historical data in pivotal clinical trials) and (Adaptive pediatric investigation plans). Here we took advantage of the occasion, where Franz was in Copenhagen visiting Lundbeck for a different purpose, and invited him to present at a DSBS event as well. We would like to encourage members to contact us if they, in a similar manner, become aware of guests in the area who could be relevant as speakers for a DSBS audience – Then we can try to invite them and plan such an event.

On November 27, 2018, an introductory course to R was held at Novo Nordisk a / s. This course is followed by two half-day events: One on R and survival analysis at Leo Pharma, and one on R and Markdown & Tidyverse at Novo Nordisk.

We have evaluated that among our members there is interest in having these half-day events on R within special statistical disciplines, so we expect to continue to have such events in the coming years. So far we have planned two upcoming events on R and multiplicity as well as R and shiny apps.

In January / February 2019, the third round of the course 'Survival Analysis in Clinical Trials' was held. Per Kragh Andersen, KU and Henrik Ravn Novo Nordisk were again lectures at the course. There was room for 35 participants, and the course was not fully booked, this time. Again, the participants were very happy with the course. We do not think that there will be sufficient audience for a round 4 in 2020, but maybe in 2021.

The board would like to thank our company members for supporting our activities with locations and catering and we hope that we can continue to benefit from your kind hospitality also in the future.

In addition, DSBS is dependent on the members scientific contributions at our meetings and we are pleased to see that many still want to participate in our events.

Brexit has hit EFSPi during the last year. EFSPi has been established as an organization in Denmark (ngo), which has required that there was appointed a Danish director. This is a position that we think should be filled with a member from or a representative of DSBS's board – and the first has become Mette Krog Josiassen. To ensure that no one will be personally liable at any time, the EFSPi has purchased an insurance for the council so that the entire EFSPi council is now covered.

In 2020/21, in addition to the previous mentioned half-day meetings on R, we plan to host two courses and two joint events with DSTS: in September a course is planned on adaptive design with Christopher Jennison, and in February a course is planned on causal analysis with Arvid Sjölander. With DSTS we are planning a go-home-like event on graphic presentation of data and potentially a two-day meeting in the fall (@DTU) on big data / AI. In addition, we would like to have resumed the tradition with DSBS commenting on guidelines / points to consider documents from the regulators, so members who become aware of relevant such guidelines in review: please contact the board and we will plan a discussion meeting and coordinate comments for submission.

The DSBS website, for many years, has been hosted by a web hotel, which by the end of June, has decided to stop providing this kind of services. We therefore need to find another solution for our website. In the same connection, we have decided to update the website - not because we are dissatisfied with the current pages - rather because we need to recognize that the current members of the board have limited competences and interest in programming HTML pages. We are therefore interested in a solution where the webmaster, designated at any given time, easy can upload content and make other modifications to the page. If there are members who have experience and interest in how these kinds of solutions are implemented, then Henrik would very much like to hear from you!

One last issue I want to address is our membership fees: The regulations of DSBS currently states, that you can become a member if the company where you are employed, is a member, or if the board assigns an individual membership to you. The membership fee for company membership is 3000 kr/year on top of which come individual membership of 150 kr/year per member from the company. For several years, the board has discussed that this construction creates great inequality among the members we have, as we have a few, relatively large member companies and a number of very small member companies. For a one-man or two-man company, the company membership seems relatively large, whereas for the larger companies it seems small. At the same time, DSBS has accumulated assets over several years - this year, we again made a small surplus, despite our attempts to avoid this. Therefore, the board would like to propose to the general assembly to change the company fee to 50 kr/year and the individual membership fee to 175 kr/year. Gabriela Martinez Ravn will present the financial implication of this in her presentation of the accounts and budget and we suggest to vote on the subject.

Finally, I would again urge members to come forward with ideas and topics for coming events such as courses and/or scientific meetings.

10 DEC 2019

A handwritten signature in blue ink, appearing to be 'Bryant J.', written in a cursive style.

12 DEC 2019

A handwritten signature in blue ink, appearing to be 'Lynn H. Bryant', written in a cursive style.

