

European Society of Toxicologic Pathology e.V.

Minutes of the Annual General Assembly held on 19th September 2019, 11:00-12:45 Köln, Germany

61 members attended

1. Welcome and Introductory Remarks

The meeting was opened timely by the chairman, Anna-Lena Frisk, who welcomed the members to the meeting. She stated that the invitation was conforming to the constitution and had been sent out timely, and thus the assembly had a quorum.

A minute of silence was held for Professor Dr. Georg Krinke who had sadly passed away during the last year.
2. Approval of Agenda

Gabi Pohlmeyer-Esch as secretary had circulated the agenda to the membership prior to the AGA. No changes were made, and the agenda was approved by the membership and the Executive Committee (EC).
3. Approval of Minutes of Annual General Assembly, 2018, Bagsværd/ Copenhagen

The minutes of last year's AGA had been circulated to the members by Gabi, prior to this AGA. There were no comments or questions, and the minutes of the Annual General Assembly 2018 in Copenhagen were approved by the assembly and the EC.
4. Report of the Executive Committee: ESTP Highlights and Achievements of Past Year

The chairman Anna-Lena Frisk presented the ESTP highlights and achievements of the past year to the membership.

Firstly, she thanked the ESTP EC members for their hard and dedicated work; without their enthusiasm and the commitment of every single EC member the ESTP would not exist.

She thanked Erio Barale-Thomas, Vanessa Schumacher, Xavier Palazzi and Pierluigi Fant for organizing the ESTP International Expert Workshop on the "hot topic" "Digital Pathology". The face-to-face workshop directly after the congress will permit an exchange between scientists and regulatory agencies. The series of ESTP Expert Workshops has proven very successful in the past, and the board would like to see it continue.

Anna-Lena mentioned the many educational activities ESTP is involved in, such as INHAND, GoReni, Classic Examples and the contribution of the ESTP to the ESVP/ECVP summer school. The INHAND nomenclature is close to being complete and published, and Anna-Lena thanked the ESTP responsables for GESC and GoReni for their work. This year's ESVP/ECVP Summer School took place in Valencia (Spain). On behalf of the ESTP, Giovanni Pellegrino gave a presentation about professional opportunities for young scientists in toxicologic pathology. Similarly, the ESTP will sponsor a talk by Jürgen Funk at the ESVP/ECVP/ECVCP meeting in Arnheim (NL). Anna-Lena thanked both persons for their enthusiasm. She also thanked the organizing team of the very interesting "Classic Examples" seminar in February 2019.

Furthermore, the society is grateful to Emmanuelle Balme for publishing the newsletter.

Concerning the Society Journal *Toxicologic Pathology* (TXP), Anna-Lena informed the members that Susan Elmore (Editor-in-Chief) would report on the journal achievements the next day of the congress. Catherine Botteron's work as Associate Editor is greatly appreciated and represents our society very well.

The Committee for Scientific Standards, chaired by Annette Romeike, is currently elaborating an ESTP response letter to the FDA draft guidance on peer review. Anna-Lena thanked Annette, Erio and the other committee members.

Angele Breithaupt as Councillor for the Younger Generation is investing a lot of effort into the promotion of our profession and our society to young pathologists in training. Under her initiative, flyers promoting industry internships have been conceived and will be distributed. There have already been positive responses, and Anna-Lena asked the members to contact Angele if they become aware of an internship opportunity.

Rupert Kellner is continuously improving the website, and Anna-Lena thanked him for this. She also reminded the members to take part in the "Guess What" quiz. Thanks to Award Committee, chaired by Hans Harleman, this year's awards will be handed out at the congress dinner.

As the administrative work within the EC is increasing, the EC members agreed to seek expert help on data protection and tax affairs.

The organization of ESTP congresses was ensured by Solution Office for many years, and Cologne is now the last congress organized by them. This is due to Solution Office's decision to no longer organize congresses outside Germany. Therefore, the ESTP EC had to seek offers, and chose a new professional congress organizer (PCO) on the basis of seven offers received from PCOs from various European countries. Decision was made for "Pauwels", a Dutch PCO which happens to organize this year's ESVP/ECVP/ECVCP congress in Arnheim (NL). For the ESTP they will organize, for now, the congresses in 2022 and 2023.

For the Cutting Edge Pathology congress in Torino, Italy (2020), an Italian PCO will ensure the organization. Pierluigi and Raffaella Capobianco will co-chair the SOC and work closely with Enrico Bollo and Bartolomeo Biolatti (LOC). The ESTP EC will have additional work through this change, but feels confident that it will run smoothly. In order to improve the communication among the co-organizing societies, it was decided that an ESTP and ECVP representative will assist all preparatory ESVP meetings. In addition, Anna-Lena will be in Arnheim next week to communicate with ESVP and ECVP. For future congresses beyond 2020, both the ESVP/ECVP and the ESTP have orally agreed to use the PCO under contract with the ESTP, in order to ensure continuity and ensure economic costs.

Anna-Lena thanked Pia Schröder and Jan Steinke and their teams for

the excellent congress organization. Also, the SOC, co-chaired by Sibylle Gröters and Björn Jacobsen, has done a fantastic job with an exceptionally attractive program. The exhibitors and sponsors were thanked for their generosity.

Lastly, Anna-Lena repeated her gratitude to all EC members and other members active for the society. She encouraged all members to support the society actively and encouraged them to approach Gabi or herself if they were willing to work within the EC.

5. Report of Scientific Organizing Committee and Local Representatives

The Scientific Organizing Committee 2016 comprised 16 members and was co-chaired by Björn Jacobsen and Sibylle Gröters. Björn presented the team members from various companies and countries and thanked them for their hard work. Starting in April 2018, they had held 18 preparatory TCs before the congress. A shared computer drive located at the Fraunhofer Institute had been of great help for sharing documents, and he thanked Rupert for this.

Björn presented the program including satellite meetings and shared sessions with the European Teratology Society and thanked the organizers. As a new concept, he presented the “break out” sessions during the lunch breaks for companies to present their technology.

He mentioned 57 posters being exhibited from Tuesday until Friday and the awards which would be handed out.

According to the latest status, there were 202 congress participants, from which 97 were members and 99 were non-members, 6 were students and 76 had registered for the IATP session.

The total income of approximately € 175,000.00 is generated from sponsors and exhibitors on the one side and (€ 95,000.00) and registration fees on the other (€ 80,000.00). The expenses (venue rent, technical equipment, furniture, catering, congress dinner, welcome reception, travel costs for speakers, registration costs, professional congress organization, tax adviser, and others are estimated to add up to approximately € 158,000.00.

In total there were 30 companies supporting this congress, and Pia had to decline some exhibitor requests due to the lack of space. The major sponsors were Airamatrix (including satellite meetings/breakout sessions), Deciphex, TPL and Pfizer (donating directly to the ESTP).

6. Questions & Answers: Pre-Circulated Reports of Committees and Councillors

Prior to the meeting the membership had received the reports of the committees and councillors. No questions were asked during the AGA.

7. Financial Report and Membership Fees

Gabi presented the financial report on behalf of our treasurer Kuno Würsch, who was absent due to illness.

Main activities/achievements of the treasurer since the last AGA meeting had been:

- Successful migration to the new online payment platform (Stripe)
- Credit card fees lowered to 1.5-2%

- Banking fees lowered to 70 € per month
- Job adverts adding up to ~ 20% of the total revenue
- Donations making up ~ 20 % of the total revenue

Gabi then presented the categories of expenses, the income statement and the balance sheets of the ESTP. This does not include the congress budget which is managed by the PCO on a separate congress account.

The expenses of 2018 are made up of congress costs, Classic Examples, INHAND fascicles, bank and credit card fees, donations, Fraunhofer GoReni, Expert Workshop, awards, administration, some Executive Committee expenses, etc. The income is made up of membership fees, registration fees for Classic Examples and Expert Workshop, advertisements, donations and CD-ROM sale. In total a surplus of € 4.855,00 was achieved.

In comparison to 2017 there are little changes, and finances show a stable situation. The net asset is steadily increasing per year. At the beginning of September 2019 our balance shows a surplus of € 22.908,00. This is the expected situation at this time of the year, but a lot of payments will have to be made until the end of the year. In a worst case scenario, the budget for 2020 could add up to a NET loss of approximately € 4.000,00.

There are currently 312 society members from 23 countries including 5 honorary members and 21 members paying a reduced fee (student and retired members). 230 have already paid for 2019, 23 have not paid yet for 2018 and 4 are behind for 2017. It is suggested to maintain the membership fee for 2020 at € 80,00 for regular fee and and € 35,00 for reduced fee.

Two comments were made from the membership: Relatively high expenses for the Classic Examples seminar in 2018 may be explained by the celebration of its 25th anniversary (special dinner), and it was suggested that the wording “profit” on one slide should be replaced by “surplus” as the ESTP is a non-profit organization.

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| 8. | Report of the Auditors | Prior to the AGA Wolfgang Kaufmann and Pierre Maliver had checked all balance sheets and confirmed the adequacy of the financial presentation, which they confirmed to be a true view of the society's treasury. Wolfgang confirmed that they had found the accounts in excellent order, recommended their acceptance and the exoneration of the EC members. |
| 9. | Vote: Exoneration of Executive Committee | The assembly accepted the accounts by vote (for: 61; against: 0; abstention: 0) and approved the activities of the board, including the membership fees. The EC has herewith been exonerated. |
| 10. | Confirmation of Auditors | The chairman thanked the auditors for their work.

The assembly approved of the continuation of Wolfgang Kaufmann and Pierre Maliver as auditors. Both had previously agreed to continue in this position. |
| 11. | Data Protection | Lars Mecklenburg presented the current topic of ESTP's compliance with the new EU general data protection law. A working group of the board had looked into the obligations a society had, and decided to seek professional advice. After a first discussion, the expert lawyer |

had concluded that the ESTP does not need a formal data protection officer, but it will need two different privacy statements for a) members and b) non-members. Also, the sharing of data with external partners, such as the PCO and others must be regulated by contract, and the conditions of data storage need to be defined.

Further services by the lawyer will be the following:

- review ESTP internal procedures for data collection and storage
- prepare a formal list of all data management activities (German language is sufficient)
- prepare a data privacy statement for non-members (in German and translation into legal English)
- prepare a data privacy statement for members (in German and translation into legal English)
- prepare a contract template for data processing by Third Parties (in German and translation into legal English)

In total, these initial services will add up to approximately €5.000 and should be completed by the end of October. For further (annual or case-by-case) support the expert can be contracted on an hourly basis.

12. New Members

The secretary presented the list of 16 new members since the last AGA, who fulfilled all constitutional criteria for membership and had therefore been approved by the EC during one of their monthly TCs.

The new members were warmly welcomed to the society. They are (in the order of entry date):

- Sijoon Lee
- Nadine Stokar-Regenscheit
- Leslie Bosseler
- Bieuc Cossic
- Ilona Kareinen
- Krystyna Siudak
- Simone Tangermann
- Anna Knuuttila
- Jonathan Carter
- Josep Monne Rodriguez
- Robert Kreutzer
- Marianna Rosentsvit
- Emmanuel Loeb
- Stephan Schmidbauer
- Dania Villarnovo
- Hanna-Kaisa Sihvo

13. Proposal and Ratification of Representatives for Sister Societies/ Other Bodies

Prior to the AGA, the secretary had asked sister societies to nominate their representatives within ESTP. The following representatives had been (re-)nominated by the societies and were acclaimed by the AGA.

French Society (SFPT): Béatrice Gauthier

Dutch Society: Eveline de Rijk

Hungarian Society: György Selenyi

British Society (BSTP): Zuhail Dincer

14. Possibility of

The EC decided to postpone this topic to the next AGA. It had been

Transfer of Society Headquarters and Discussion

discussed intensely by the EC during the F2F meeting on Monday, and it had been concluded that there is not yet enough information in order to advise the membership.

Briefly, Anna-Lena summed up the main reasons why moving the ESTP headquarters to Switzerland or another country seems advantageous. The main reason is the complex tax legislation in Germany, leading to a high workload for the treasurer. The EC will continue to investigate and will consult other societies for their experience with headquarters in Switzerland (ETS) or The Netherlands (ECVP).

15. News from Committees and Discussion

To serve as examples, the EC had chosen to focus on the reports of three committees: the Committee of Scientific Standards (CSS), Committee Pathology 2.0 and Committee for Clinical Pathology and Biomarkers.

Committee for Scientific Standards (CSS)

Annette presented the current situation within the CSS, which has only five members. New active members are needed for the TCs held every two months and one F2F meeting per year. The considerable importance of the CSS lies in reviewing and responding to Draft regulatory guidelines (FDA, OECD etc.) which impact the work of toxicologic pathologists directly. Other tasks of this committee are to review Best practice paper manuscripts, inform members about changes in the regulatory environment and ensuring the link to the STP Scientific and Regulatory Policy Committee.

Currently, commenting the FDA draft peer review guidance is of greatest importance and urgency (deadline for comments postponed to the end of October). Another future focus of the committee will be to think about topics which are of interest to TXP and invite experts to write position papers and opinion papers. Members interested in contributing to this committee are asked to contact Annette.

Clinical Pathology and Biomarkers:

Currently the committee is looking for a new chair as Aida Diaz-Bayon wishes to resign. This committee has made valuable contributions to the ESTP (webinar on hematology in 2018), but needs to re-define its aims focus. There is only a small number of active members in this large group.

Pathology 2.0

Thomas Lemarchand wishes to resign as chair, nevertheless the EC hopes for the committee to revive and become more active due to its valuable contributions since 2012. Especially as the congress topic is "their topic" the members were invited to join a F2F meeting after this AGA in order to capture new active members.

"Golden Rules"

The EC proposed to have a list of "Golden Rules" for the committees in order to promote more productive activity. They would include activity of the chairs and members, the minute writing and the commenting of the minutes.

16. News from Society Journal

The ESTP Associate Editor of TXP, Catherine Botteron, presented the journal achievements to the members. In 2018, 227 manuscripts were

and Discussion received, which is an increase of 11.8% compared to 2017, and 58% of the manuscripts were accepted. The average time for making a decision was 20 days.

Within the Journal there is an Editor-in-Chief, 14 Associate Editors (term: two years) and 56 editorial board members (term: one year), including five biostatisticians. Catherine described how she proceeds when being assigned a manuscript.

She stated that ESTP members can contribute to TXP in various ways, by submitting manuscripts, volunteer as editorial board member, reviewing manuscripts or proposing reviews on a specific topic.

The ESTP has just decided on a new SOP on how to formalize the process of publishing papers under the ESTP banner. Annette explained that publications from the ESTP Expert Workshop, Committees, Working Groups or individual members can be handed in and will then be endorsed by the ESTP prior to publication under an ESTP banner.

17. ESTP International Expert Workshops

Xavier updated the members on the status of the manuscript resulting from the 6th Workshop (“Adversity of Thyroid Follicular Epithelial Hypertrophy/Hyperplasia”) held in Berlin 2018. A pre-final version of the publication is still being reviewed by some experts and is planned for TXP with endorsement by major national and international societies.

The 7th Workshop “Towards Regulatory Acceptance of Digital Toxicologic Pathology” takes place right after this congress in Cologne. The main goals are

- to define a set of minimal requirements needed to grant future regulatory acceptance for the use of digital toxicologic pathology workflows in R&D
- to review whole-slide scanner validation, acceptable data/metadata formats, digital slide transfer, processing, evaluation/analytics, storage, viewing, annotating and archiving processes
- to compare with current practices in diagnostic medical radiology and pathology
- to discuss practical limitations of digital pathology (e.g.: resolution, technical requirements, archiving costs)

Ten preparatory teleconferences before the workshop had been held by an expert panel composed of 26 international experts and members of the ESTP. The aim is a publication in TXP, with endorsement by major national and international societies. Posters are planned for JSTP (January 2020), STP (June '20) and ESTP (September '20) meetings.

Anna-Lena emphasized the wish of the ESTP to hold future ESTP International Expert Workshops and asked the members for input. This could be a follow-up on Digital Pathology or another topic, and, depending on the circumstances and topic, could be organized as satellite event to a congress or independently.

- 18.** Presentation of 2020 Cutting Edge Meeting in Torino, Italy
- Raffaella and Pierluigi, co-chairing the SOC 2020, presented the invitation to the 2020 Cutting Edge Congress in Torino. It will be the 4th joint “Cutting Edge” congress and will be held from the 26th-29th August 2020 in collaboration with the University of Veterinary Medicine in Torino. The topic will be “Biomarkers and Organ Toxicity”. So far, the SOC had held three TCs and one F2F meeting. The scientific program should be set by the end of 2019. It will consist of joint keynote lectures, some parallel sessions specifically for ESTP and ESVP/ECVP, INHAND sessions, case presentations and poster sessions. As always, IATP will hold a satellite session before the congress on Wednesday morning.
- The venue will be a newly built university building in the center of Torino, in the North of Italy. The chairs of the LOC are Bartolomeo Biolatti and Enrico Bollo. Any more volunteers for the SOC are welcomed to contact Pierluigi. Any comments or general suggestions regarding this meeting are welcomed by Anna-Lena.
- 19.** Announcement: Classic Examples in Toxicologic Pathology XXVII
- Thomas Nolte announced the 27th Classic Examples seminar to be held on the 21st-22nd February, 2020. As every year, it will take place at the Veterinary School in Hannover, Germany. On Friday evening there will be an informal get-together. Ten cases from the field of toxicologic pathology will be presented. Glass slides and digital slides will be provided (the latter will be available online for four weeks prior to and after the meeting). Thomas reminded that members are always invited to hand in interesting cases.
- 20.** Any other Business
- Lars asked the members if there was any interest in another workshop on medical writing. Such a workshop had been offered during the Cutting Edge Congress in Berlin in 2014. A new workshop would be feasible in 2020 or 2021.
- At the AGA, one members welcomed this initiative and emphasized that pathology reports must be written in such a way that they can be understood by non-pathologists.
- The chairman closed the Annual General Assembly timely.

Dr. Gabriele Pohlmeier-Esch
Secretary, ESTP

Dr. Anna-Lena Frisk
Chairman, ESTP