

European Society of Toxicologic Pathology e.V.

Minutes of the Annual General Assembly held on 29th September 2010, 5-7 pm Budapest, Hungary

64 members attended

1. **Welcome**

The meeting was opened by the Chairman, Ingrid Sjögren. She warmly welcomed the members to the meeting and stated that the invitation had followed the rules set by the constitution and thus the assembly had a quorum.
2. **Agenda**

The previously circulated agenda (sent out on July 29th to the membership) was accepted. Ingrid pointed out that in contrast to previous years the individual committee/councillor reports will not be presented in detail. This would allow more time for questions and for the discussion of item no. 15 (peer review and education). Item no. 16 (report of the local organizing committee) was cancelled due to the absence of Dezsö Dányi. All committee/councillor reports have been circulated about 2 weeks prior to the meeting to all members.
3. **Approval of Minutes from The Hague 2009**

The minutes of the Annual Meeting held in The Hague, Netherlands had been circulated to the membership by e-mail on November 26th 2009, and were accepted as a true record.
4. **Annual Report of the Executive Committee**

Ingrid Sjögren presented the executive committee report.

The report of the executive committee activities of the last year had been previously circulated by e-mail. In addition it will be put on the website after the meeting, so that Ingrid touched only a few topics of major interest.

She informed the membership that elections would take place and listed the current committees. A new committee, the News committee, was created, lead by Zuhai Dincer. Members were encouraged to contact Zuhai in case they would like to be actively involved in this committee. On the other hand, it was decided to dismiss the Case committee, which existed since the congress in La Grande Motte 2006 and was lead by Sibylle Gröters, since no cases have been submitted during that period.

The congress policy document was updated. It had been created to serve as a reference for the organization of future congresses (rules and processes). The minutes of the executive committee teleconferences and meetings are now prepared by Amy Narewski from Solution Office. Amy's assistance in minute taking is very helpful and relieves the secretary of some of the administrative work. In addition, the selling of CDs from the Classic Examples is now handled by Solution Office. Ingrid expressed a special thank you to Mrs Blankenfeld, who took care of this task in the past and who retired.

The issue of non-paying members was addressed during the last year

and resulted in a proposal for a change in the Constitution, which will be discussed under item 9.

The ESTP was active in the INHAND initiative. The respiratory tract was published as the first organ system. The liver will be next for publication. The nervous system manuscript is also expected to be ready for publication soon. The ESTP was involved in the discussion about peer review and training for toxicologic pathologists. Specifically the ESTP executive committee and Guideline committee have been extensively involved in the review, commenting and finalization of two manuscripts dealing with very important topics:

- Recommendations for Pathology Peer Review. [Morton et al. Toxicol Pathol 0192623310383991, first published on October 5, 2010 doi:10.1177/0192623310383991]
- International Recommendations for Training Future Toxicologic Pathologists Participating in Regulatory-Type, Nonclinical Toxicity Studies. [Bolon et al. Toxicol Pathol 38: 984-992. 2010 doi: 10.1177/0192623310378137]

The next ESTP congress will take place 7. – 10. September in Uppsala, Sweden as a joint congress with ESVP and ECVP. The seminar Classic Examples will take place 18. – 19. February in Hannover, Germany.

Finally Ingrid thanked the organizers of this congress for their good work.

There were no questions from the membership.

5. Questions to the reports of the respective committees and councillors

The following reports have been pre-circulated:

Award Committee, Guess What Committee, Guideline Committee, Membership Committee, Journal Councillor, Newsletter Committee, Younger Generation Councillor, IFSTP Councillor. Short summaries of the individual reports are attached in Appendix 1.

There were no questions from the membership on the reports.

6. Financial Report

The financial report was presented by Matthias Rinke. He explained the details of credits and debits to the membership.

Balance on 31 December 2009: 28.370,69 € (credits August – December 2009: 24.129,31 €, debits: 23.851,56 €)

Balance on 25 August 2010: 47.123,94 € (credits January – August 2010: 32.630,23 €, debits: 13.876,98 €)

Balance 22 September 2010: 49.007,22 € (credits August – September 2010: 2.081,07 €, debits: 197,79 €)

Furthermore, Matthias informed about the financial details of past congresses: in Basel 2007 a plus of 36.415,28 € is to be split between ESTP and IFSTP; Edinburgh 2008 resulted in a deficit of 5.485,13 € which will be shared by ESTP and ETS 50/50% (the final bill is still open due to the U.K. tax law); the congress in The Hague 2009 is in progress, it might result in a deficit; for the current congress in

Budapest a plus of 24.500,00 € is estimated.

In addition, the topic of non-paying members was addressed. Currently there are open credits of 21.800,00 €, of which 12.500,00 € are membership fees. The difference of 'expected' to 'actual' membership fees is 9.300,00 €, based on the number of members that have not paid for the third year in a row. These members will be excluded by the end of 2010 (according to the current rules in the constitution), the distribution of the journal was stopped and the fascicles (INHAND) were not provided.

Matthias presented the answer to a question from last year: he investigated whether it would be possible to add Amex to the list of credit cards that are accepted by the ESTP. This is however too expensive and only two members asked about payment with Amex.

There was a question from a member, if ESTP could loose the non-profit organization status in context with the German tax laws in the future, if we exceed a certain amount in wealth. Matthias answered that this is not very likely, since we have deficits with our congresses.

7. Report of the Auditors

Agnes Schulte and Jean-Claude Schaffner reported that the accounts were in excellent order and praised Matthias Rinke for his extraordinary work. They have checked all balance sheets and confirmed the adequacy of the presentation, which is a true view of the treasury. They recommended acceptance of the accounts. The members accepted the accounts unanimously and approved the activities of the Board. The executive committee has been herewith exonerated. The statement is attached as Appendix 3.

8. New members

Annette Romeike presented the list of new applicants. They were accepted into the Society without objection.

1. Nanna Elsborg Grand - 25 November 2009
2. Karen Regan - 25 November 2009
3. Silke Glage - 20 January 2010
4. Ansgar Buettner - 20 January 2010
5. Julie Mou Larsen - 20 January 2010
6. Keith Nelson - 20 January 2010
7. Robert Maronpot - 23 February 2010
8. Fiorella Belpoggi - 29 April 2010
9. Björn Jacobsen - 29 April 2010
10. Céline Thuilliez - 29 April 2010
11. Eric Spicer - 29 July 2010
12. Nabil Hailat - 01 September 2010
13. Srinivas S. Rao - 01 September 2010
14. Qingxi Kong - 01 September 2010
15. Klaus Weber - 29 September 2010

9. Questions and Vote on Changes to Constitution

Annette Romeike presented the proposal for a change to § 5 Point 7 of the ESTP Constitution, which should reduce the administrative burden related to non-paying members:

Current version:

§ 5 Membership

7. Membership is terminated

- a. when a member dies,
- b. by a written note of resignation, addressed to a member of the executive committee; this is only possible at the end of the calendar year with 3 months notice,
- c. by expulsion from the society,
- d. after three years non-payment of membership fees.

New version:

§ 5 Membership

7. Membership is terminated

- a. when a member dies,
- b. by a written note of resignation, addressed to a member of the executive committee,
- c. by expulsion from the society,
- d. after one year of non-payment of membership fees.

The proposal was unanimously accepted by the membership.

Matthias Rinke encouraged members to update their profiles on the ESTP website (members' section) where necessary, especially any changes in e-mail addresses. If members have forgotten their password, they should contact the ESTP secretary.

10. ***Election of Councillors and Executive Committee***

By decision of the executive committee Wolfgang Kaufman has been co-opted to lead the elections. Each of the following recommendations of the executive committee were proposed one by one and approved as stated (except the Chairman and Past Chairman, since they are defined by the constitution). In consistency with the constitution, the recommendations had been sent to the membership more than 2 month prior to the election. Catherine George and Wolfgang Drommer wished to retire from their positions and suggestions from the membership to fill the vacancies with Paul-Georg Germann (Councillor for IFSTP) and Wolfgang Baumgärtner (Councillor for the University Teachers) were received. No further proposals had been received for any of the other positions:

Chairman	Annette Romeike – automatically by constitution
Designated Chairman	Frédéric Schorsch – approved (62 Votes for, 1 against and 1 abstention)
Past Chairman	Ingrid Sjögren – automatically by constitution
Vice Chairman	Ursula Junker Walker – unanimously approved (62 votes and 2 abstention)
Secretary	Francesco Marchesi – unanimously approved (63 votes)

	and 1 abstention)
Treasurer	Matthias Rinke – unanimously approved (63 votes and 1 abstention)
IFSTP Councilor	Paul-Georg Germann - unanimously approved (63 votes and 1 abstention)
Councilor for our Journal	Birgit Kittel - unanimously approved (63 votes and 1 abstention)
University Professor	Wolfgang Baumgärtner - unanimously approved (62 votes and 2 abstentions)
Councilor for Younger Generation	Sibylle Gröters - unanimously approved (62 votes and 2 abstentions)
Councilor for Electronic Communication	Rupert Kellner – unanimously approved (63 votes and 1 abstention)

Ingrid Sjögren welcomed the new members and thanked those that leave the executive committee (Catherine George, John Finch and Wolfgang Drommer) for their contributions.

11. Election of sister societies or other bodies to be represented on the Executive Committee

Annette Romeike explained that sister societies are nominated according to the constitution. The following societies have been re-nominated and were unanimously accepted by the membership:

French Society of Toxicologic Pathology
Dutch Society of Toxicologic Pathology
Italian Society Toxicologic Pathology
British Society of Toxicologic Pathology

The following new society was nominated as sister society and unanimously accepted by the membership (62 votes and 2 abstentions):

- Hungarian Society of Toxicology

12. Proposal/Nomination of Representatives for sister societies/other bodies

Annette Romeike explained the process. Sister societies nominate representatives to the ESTP executive committee, who are then elected/ratified by the ESTP membership. The following representatives were proposed Erio Barale-Thomas as representative for the French Society, Frieke Kuper for the Dutch Society (replacing Bob Thoolen), Francesco Marchesi for the Italian Society and György Selényi for the Hungarian Society. The BSTP has not nominated a representative until now. Thus, no representative will be proposed for the BSTP.

13. ***Election/Ratification of Representatives*** The formerly proposed representatives were unanimously accepted by the membership. Ingrid Sjögren welcomed them to the executive committee.
14. ***Election of Auditors*** Jean-Claude Schaffner needs to retire as Auditor due to retirement. Daniel Roth volunteered to replace Jean-Claude Schaffner and was unanimously elected (63 votes, 1 abstention). Agnes Schulte was unanimously accepted by the membership (64 votes and no abstentions).
15. ***Membership Discussion on Important Topics (Peer Review; Education of Toxicologic Pathologists)***
1. During his talk, Erio Barale-Thomas provided, as background information, the presentation he made at the STP Symposium in Chicago (June 2010) on the Pathology Peer Review topic and related discussions. Erio subsequently presented the current status of the elaboration of ESTP membership comments on the circulated U.K. GLPMA (MHRA) draft guidance on Pathology Peer Review. He emphasized the current challenges for peer review and why pathology data deserve a certain exception status amongst raw data.
- Discussions on the OECD draft guidance on pathology peer review are ongoing. The current status is as follows:
- An initial draft was compiled by Andrew Gray from MHRA-U.K.
 - An OECD working group was created, lead by Andrew Gray and with representatives from various countries
 - The first draft is open for public comments until end of October 2010
 - BSTP and STP have already finalized their sets of comments
 - Comments are also compiled by other institutions (non-STPs), e.g. EFPIA and the corresponding organization in the US, national societies of Quality Assurance. Individual companies might also send their comments.
 - The ESTP asked their members for comments and many were received and therefore showing that the topic is of great interest for the members. The comments will be compiled, put into context and sent to the OECD. The ESTP position is supported by the French and Italian Societies. The STPs plan to harmonize their comments and make sure that there are no major discrepancies between the societies before they are sent to the OECD (Andrew Gray). In addition, the IFSTP will send a letter stating the STPs are supported by them.
- The comments made by the membership during the discussion can be summarized as follows:
- It was emphasized that the STPs need to prepare for negotiations and create a dialogue with the regulators and inform them about the peer review process and the important aspects. ESTP should be very careful when addressing requirements for the conduct and reporting of Pathology Peer Review with the regulatory authorities. Negotiations might result in more extensive requirements for

documentation, which would contribute to the ever increasing requirements for documentation without concomitant increase in the quality of the data.

- STPs from the different geographic regions should build a strong common position, reiterating their arguments in support of the practice to conduct pathology peer review on draft pathology reports. Annette Romeike pointed out that the ESTP opinion will be in line with the best practice paper that is currently being published by the STP. One member commented that the impression deriving from the content of the circulated draft guidance is that the regulators do not want to make a distinction between draft and final reports. They simply want to achieve increased control over the pathology peer review activities in order to detect undue influence on pathology data and reports.
- Concern was raised by the membership that peer review might only be the starting point and that also other processes, e.g. the reporting process, might be challenged. It is therefore important to state that peer review is done to increase quality.
- Another comment indicated the need for the pathologists to convey the concept of pathology as a clinical discipline, which further reinforces the importance of interpretation of data.
- Questions raised were about whether peer review is compulsory or mandatory and when are pathology data raw data.
- Authorities may want to trace who is responsible for what and which contribution is from whom. Arguing with them might not be successful. Traceability is one aspect, but in addition it might be required to explain why there are differences between study pathologist and peer reviewer.
- Dialogue with authorities is important. It is also a question of trust, therefore building trust with regulators is important.
- It is technically feasible to lock data when using pathology data capture systems, although it would be preferred to stay with the current practice. CROs might choose to lock the data, if they want to. There would be no need for a specific guidance.
- It is still possible that the regulators might step back from the proposal like they did with the original guideline for phototoxicity.
- Pathologists who sign a report are professionals and their reputation is directly involved in their role as contributory scientists for preclinical safety studies. For this reason they would not accept to sign anything they do not consider as an accurate description of the findings.

2. Johannes Harleman presented a proposal from the IFSTP for a training program for toxicologic pathologists (the slides will be sent out to the membership):

- Background: IFSTP was approached to provide training for their

STPs

- Objective, strategy: training modules for pathologists in emerging economies, but can be used by others as well; coordinated by IFSTP; program should run over 3 years, be attractive and use mostly existing resources; each STP takes ownership for one or more modules
- The training is Webex-based, run from server of French STP, slide sets should be made available as scanned slides
- Faculty includes volunteer lecturers from the STPs; organ based program, possibly with additional subjects, e.g. introduction to regulatory toxicology, DMPK, new technologies, classical examples

Proposed program: Target organ pathology, given as modules – quarterly, leader of modules to be announced

Hans asked for feedback from members about the value of the concept and volunteers for modules. Contact persons are Johannes Harleman johannes.harleman@astrazeneca.com and Wolfgang Kaufmann wolfgang.kaufmann@merck.de

The topic was discussed. One suggestion was that the training modules in toxicologic pathology from the University of Hannover, Germany, where many ESTP members are involved, could be opened to other universities and young pathologists from companies. The most recent cycle started during the winter term 2008/2009 and will finish in the summer term 2011.

One member offered that students might receive training in his/her laboratory.

BSTP offered guidance and indicated that the technical aspects for such a program would not be trivial.

16. Report of local Organizing Committee

Was cancelled due to the absence of Dezső Dányi (chair).

17. Any Other Business Honorary Membership

Gerd Morawietz was proposed for honorary membership. He has provided excellent support for our society e.g. with the establishment and maintenance of the website, CDs for the Classic Examples and former congresses and was also involved in congress organization and in the RITA/INHAND projects. The proposal was accepted unanimously by the membership.

Miscellaneous:

- A member raised concern about the quality of the journal, which is perceived as poor. Ingrid Sjögren replied that the executive committee is aware of it and is discussing it. Birgit Kittel asked for comments/examples from the membership in the past, but has received only little feedback so far.
- The question was raised, if an age distribution survey of our

members (anonymous) could be provided. Annette Romeike addressed this question. No information about the age of members is available in the membership database.

- Another question was about multiple memberships of ESTP members in different societies. Annette Romeike replied that this information is not completely available.

Finally, Annette Romeike thanked Ingrid Sjögren for her contributions during the last years. Ingrid thanked the members of the executive board and all members for their support and closed the meeting.

Annette Romeike
Secretary, ESTP

Ingrid Sjögren
Chairman, ESTP