

Proposal to introduce an accreditation on European level

- Background
- Why
- EFSPIs draft Proposal
- Questions
- Discussion







Accreditation is a process in which <u>certification</u> of competency, authority, or credibility is presented

Professional certifications are earned from a professional society.

- In general, must be renewed periodically, or may be valid for a specific period of time.
- As a part of a complete renewal of an individual's certification, it is common for the individual to show evidence of continued learning.
- Most certification programs are created, sponsored, or affiliated with professional associations ... interested in raising standards.
- The growth of certification programs is also a reaction to the changing employment market.





- Voluntary accreditation exists within several professions (especially skill based trades)
- Accreditation of statisticians has been much discussed over last 15 years
- Variety of national European statistical associations have accreditation for statisticians
- ASA has currently implemented an accreditation for Professional Statisticians
- No European wide accreditation system exist and no system focuses
 exclusively on pharmaceutical statisticians





- Pharmaceutical statistics becomes more technical and innovative, therefore it becomes more important to ensure that statisticians are appropriately qualified
- Statisticians are moving across countries more often
- Desire to demonstrate skill sets and professional development in consistent and measured way to

Employers, Peers, Regulatory authorities, ...





EFSPI is developing a proposal to introduce an accreditation system on European level:

- Target group
- Level of accreditation
- Criteria for registration
- Fee
- Renewal process
- European Registration board





Target group: Pharmaceutical Statistician

Who to cover?

 It should cover the 'qualified statistician' mentioned in GCP and requested in regulatory settings

Other o

Question:

- Stati Do you agree with the proposed target – S group of Pharmaceutical Statisticians?
- Bios
 - See Dutch system and German certification "Biometrics in Medicine"



One level: Professional level (PSTAT)

Relevant education and minimum number of years
 with professional experience

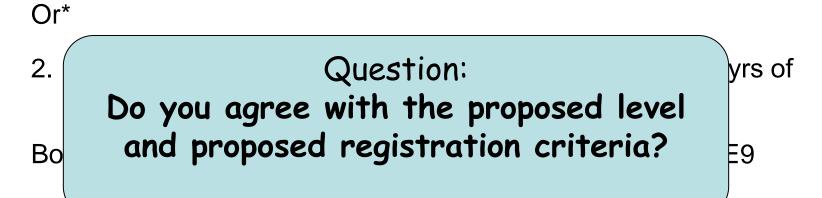
Consideration:

- Some systems with a wider scope recognize a second level to cover those who satisfy only the academic requirements
 - See Graduate Statistician (GradStat, RSS and GS, ASA)





- Combination of adequate education and relevant practical experience (on discretion of registration board):
 - MSc (or PhD) in statistics or equivalent (to be defined) and ≥ 5 yrs relevant experience with 2 yrs of personal responsibility



• Two registered statisticians to confirm relevant practical experience and professional competence

* to cope with current situation: review after 5 years whether still needed





Fee around 100 Euro

- Registration fee should be low and valid until renewal
- Should at least cover administrational costs
- No objective to make excessive profit Cou Do you agree with the proposed structure behind the registration fee?
- Annl
- No related membership is required
- Final fee depends on assessment of administration costs





- Accreditation is for 5 years
- Verify work location and position of applicant
- Keep administration as low as possible
- Same for for ronowal (to cover administrational costs) Question:
 Conside Do you agree with the proposed renewal process?
- Kee
 - no verification of basic education is needed
 - Ongoing experience will cover the required continued learning
- Fee should not discourage people to renew



Role of European registration board:

- Define rules of acceptability
- Establish and maintain overview of acceptable educations across Europe
- Verify registration criteria and make decisions
- In charge of verification at renewal status
- To maintain list of registered people



Who should be on the board:

- Members should be selected across Europe to represent main countries and education systems
- EFSPI should be represented, preferably by a (dedicated) council member responsible for it

Question: Do you agree with the proposed registration board?



- Install European registration board
- Align with existing systems and define rules how to accept current national levels within Europe
- Promote, explain and discuss this initiative
- Finally, discuss possibilities to be recognized by health authorities





Are you in favor of EFSPI's proposal to introduce a European accreditation system?

Do you agree with the proposed:

- target group of Pharmaceutical Statisticians?
- level and registration criteria?
- structure behind the registration fee?
- renewal process?
- registration board?