Editorial*
on the Qualification of a Responsible Biometrician in the Conduct of Clinical Trials

(*English translation of the original German article published in *Medizinische Informatik, Biometrie und Epidemiologie in Medizin und Biologie* 31/3 (2000), p. 103-104)

In September 1981, the German Society for Medical Informatics, Biometrics and Epidemiology (GMDS) and the German Region of the International Biometric Society (GR-IBS) established the criteria for the certificate "Biometrics in Medicine" [1]. At that time no German university offered major or supplemental courses in the field of Medical Biometrics. In this way, these professional societies expressed their intent to take active responsibility for training in the field of Medical Biometrics and to set standards for the qualifications of Medical Biometricians.

In 1987, the significance of Medical Biometrics received additional recognition through the establishment of legal admission requirements and further explication of the Notification on Principles of the Proper Conduct of Clinical Trials for Drug Evaluation [2]. These request for example adequate qualifications for the principal medical investigator, the Responsible Biometrician and the physicians conducting the examination. For the first time a Responsible Biometrician was mentioned in legal regulations on drug evaluation. At the same time the certificate "Biometrics in Medicine" received official recognition by the German Federal Institute for Drugs and Medical Devices (BfArM) as proof of qualification for Responsible Biometricians.

In the European Union approvals of drugs and medical devices are increasingly not under the authority of individual member states, but will be granted by the European Agency for the Evaluation of Medicinal Products (EMEA). The EMEA also recognizes holders of the certificate "Biometrics in Medicine" as Responsible Biometricians in the conduct of clinical trials following the ICH Guidelines [3, 4].

The certificate "Biometrics in Medicine" has thus achieved recognition far beyond the original intention when it was introduced in 1981.

The revised rules and regulations for conferring the Certificate published here take into account both this shift in significance as well as progress made in medical research and Biometrics. The Certificate "Biometrics in Medicine" certifies that the holder is qualified to assume a position of responsibility in Medical Biometrics on the basis of university education, including continued complementary education, and five years' experience in the field of Medical Biometrics. Furthermore, they are familiar with practical and methodological problems in planning, execution and evaluation of clinical studies, and possess the ability to work in an interdisciplinary context with medical scientists in various fields.

Certification in Germany not only satisfies the requirements of the national authority; it has achieved a remarkable status in the European context [5].

There is still no specific university education of Medical Biometrics in Germany, nor would this likely be desirable. Advanced studies for training in Medical Biometrics have, however, been established on the basis of recommendations of the GMDS [6]. Thus postgraduate training courses provide practical and methodological knowledge in areas complementary to the original university education. Appropriate courses are now available, and contact addresses are provided by the professional societies. Overviews of postgraduate courses in Medical Statistics in Europe are available in the sources cited below [7, 8].

Since its establishment, the certificate “Biometrics in Medicine“ has been conferred 93 times. The revision of the Regulations for awarding the Certificate published here takes into account progress made in the field and the increased importance of Medical Biometrics. All experienced Medical Biometricians are herewith encouraged to apply for the certificate “Biometrics in Medicine“.

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Regulations*
for Awarding the Certificate “Biometrics in Medicine"

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Issued by the German Society for Medical Informatics, Biometrics and Epidemiology (GMDS) and the German Region of the International Biometric Society (GR-IBS).

Developed by the members of the Certification Committee “Biometrics in Medicine“:

Uwe Feldmann (chair), Edgar, Brunner, Horst Nowak, Rudolf Repges, Peter Roebruck, Siegfried Schach, Hans Joachim Trampisch, Peter Voleske, Joachim Vollmar, Jürgen Windeler

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§ 1 The Certificate “Biometrics in Medicine“

(1) The certificate “Biometrics in Medicine“ is jointly conferred by the German Society for Medical Informatics, Biometrics and Epidemiology (GMDS) and the German Region of the International Biometric Society (GR-IBS), henceforth called the Societies.

(2) The Certificate confirms the holder’s advanced theoretical and practical qualifications in the field of Medical Biometrics.

(3) The Certificate confirms the holder’s qualification to act as a Responsible Biometrician in the conduct of clinical trials.

(4) The Societies establish the conditions for conferral of the Certificate. The Appendix to the Regulations contains the guidelines for awarding the Certificate and may be revised as needed by the Certification Committee “Biometrics in Medicine”.

§ 2 Requirements for Certification

(1) The candidate must fulfill the following requirements to receive the Certificate:

1. the completion of a university education in medicine, statistics or mathematics
2. the completion of advanced theoretical study complementary to the original course of study according to the criteria of Section 1, Number 1
3. at least five years’ practical experience in the field of Medical Biometrics
4. the completion of practical courses of study in several areas of applied Medical Biometrics
5. an oral conference with members of the Certification Committee.

(2) In individual cases a qualifying degree in fields other than those given in Section 1, Number 1 may be accepted. Recognition of special preliminary qualifications is regulated by the provisions of the Appendix.

(3) A degree granted by a foreign institution of higher learning can be accepted only if its equivalence to one of the degrees named in Section 1, Number 1 or in Section 2 can be demonstrated.

(4) Further rules applying to the requirements of Section 1, Numbers 1-5 are specified in the Appendix.

§ 3 Certification Committee

(1) Unless other regulations apply, all decisions concerning the conferral of the Certificate are made by a committee established by the Societies for this purpose.

(2) The following fields of specialization are to be represented in the Committee:
   I. Medical Biometrics (three members, three deputies)
   II. Medicine (one member, one deputy)
   III. Mathematical and statistical foundations (one member, one deputy)

At least two members or deputies must be employed in a non-university institution.

(3) Members of the Certification Committee and their deputies are nominated for the various disciplines by the Societies for a term of two years. Re-nomination is permissible.

(4) One of the members of the Certification Committee is elected by the Committee as chairperson for a term of two years. Re-election is permissible.

(5) The chairperson may nominate a secretary, who does not have to be a member of the Committee.

(6) All decisions of the Committee are made by simple majority. In the absence of a member, the deputy votes.

(7) The candidate may submit a written objection to decisions of the Committee. The decision whether to grant the objection is made by the presidents of the Societies.

§ 4 Application Procedure

(1) The candidate submits a written application for conferring the Certificate to the chair of the Certification Committee.

(2) The application is to be accompanied with documents substantiating the fulfillment of the requirements stated in § 2, Section 1. These documents normally include expert evaluations.

(3) The processing of the application is subject to a fee.

(4) Details of Sections 1 - 3 are given in the Appendix.

§ 5 Certification Procedure

(1) The Committee determines whether the candidate meets the requirements for certification as specified in § 2 on the basis of the documents submitted.

(2) If the requirements as specified in § 2 are met, the candidate will be invited to the conference by the chair of the Committee. The candidate submits three topics from his or her area of applied Medical Biometrics for the conference.
If the suggested topics are deemed appropriate, the Committee will select one for the conference.
If none of the topics submitted is appropriate for the field of Medical Biometrics the Committee may reject them.
In this case the candidate may again submit three topics. If all the topics submitted by the candidate the second time are rejected by the Committee, the Committee may end the procedure with no further justification and without issuing the Certificate.

(3) If the candidate fails to appear at an agreed appointed time for the conference for a second time, the Committee may end the procedure with no further justification and without issuing the Certificate.

§ 6 Oral Conference

(1) The conference will normally have a duration of 30 minutes, beginning with a report of no more than 15 minutes by the candidate on the topic selected by the Committee. The ensuing discussion will cover the theoretical and methodological foundations of the topic dealt with in the report with special emphasis on the practical consequences in its application.

(2) The conference is not open to the public.

(3) The Committee decides on the basis of the conference whether to confer the Certificate in accordance with § 3, Section 6. The chair of the Committee informs the candidate of the results.

(4) If the conference does not lead to conferral of the Certificate, the candidate must receive written notification of the reasons for this decision. The conference may be repeated one time with a different topic. The choice of the topic must conform to § 5, Section 2.

§ 7 Revocation

(1) The Certificate may be revoked retroactively if it is determined that the requirements were not fulfilled at the time of its conferral.

§ 8 Validity

These regulations go into effect as of August 8, 2000, at which time all previous versions become invalid.

....

(signed)
Prof. Dr. Iris Pigeot-Kübler
President of the German Region
of the International Biometrical Society
(GR-IBS)

(signed)
Prof. Dr. Rüdiger Klar
President of the German Society for Medical
Informatics, Biometrics and Epidemiology
(GMDS)

Appendix
to the Regulations for Awarding the Certificate “Biometrics in Medicine“

1. Purpose

The Certificate “Biometrics in Medicine“ certifies that the holder is qualified to assume a position of responsibility in Medical Biometrics on the basis of advanced studies and five years’ experience in the field of Medical Biometrics.

The Certificate “Biometrics in Medicine“ is recognized by the German Federal Institute for Drugs and Medical Devices (BfArM) and by the European Agency for the Evaluation of Medicinal Products (EMEA). The certification qualifies the holder to act as a Responsible Biometrician in the conduct of clinical trials according to the ICH guidelines.

2. Requirements for Certification

The requirements for awarding the Certificate “Biometrics in Medicine“ are set out in § 2 of the Regulations. These specify that the candidate demonstrates practical experience in

a) planning, conducting and evaluation of clinical therapeutic studies.

Furthermore the candidate must demonstrate practical experience in at least one of the following fields of biometrical applications:

b) planning and evaluation of prognostic and diagnostic studies
c) planning and evaluation of epidemiological studies
d) statistical analyses in the field of public health
e) preparation and empirical examination of biomathematical models
f) further development of applied statistical procedures
g) development and application of computer programs for statistical and biometrical procedures.

The areas of specialization as indicated in § 3, Section 2 are specified in the following exemplary list of topics:

I: Medical Biometrics

I.1 Theoretical Foundations

1. Linear models
2. Parametric and non-parametric procedures
3. Multiple testing and sequential procedures
4. Longitudinal data and time series analysis
5. Survival time analysis
6. Descriptive statistical methods
7. Data processing and statistical software

I.2 Applications

1. Pre-clinical studies
2. Clinical studies (therapeutic, diagnostic, prognostic)
3. Epidemiological and clinical-epidemiological studies
4. Quality management and health economics
5. Human genetics
6. Risk assessment (e.g., evaluation of adverse events of drugs)

I.3 Development of Drugs and Medicinal Products

1. Forms of studies in clinical development plans
2. Regulation of clinical studies (laws, ordinances, guidelines)
3. Ethical premises

II. Medicine

1. Medical terminology
2. Structure and function of the human organism (anatomy, biology, biochemistry, physiology)
3. Pathology, nosology, pathophysiology
4. Principles of diagnosis and therapy
5. Economic and social aspects of medicine
6. Public health

III. Mathematical and Statistical Foundations

III.1 Mathematical Foundations

1. Basic calculus
2. Basic concepts of linear algebra

III.2 Statistical Foundations

1. Probability computations
2. Statistical distributions
3. Statistical test and estimation procedures

The Certification Committee determines whether the application contains evidence of sufficient competence in these areas.

The qualifying courses of study named in § 2, Section 1, Number 1 of the Regulations for Certification are recognized as proof of sufficient competence in the following areas: a university degree in medicine, Area II; a university degree in mathematics: Area III.1; a university degree in statistics: Area III.
Depending on the qualifying course of study the candidate must demonstrate competence in the complementary areas. As a rule competence in a complementary area is acquired by the successful completion of an advanced course of study, which must be confirmed by an expert advisor according to § 4, Section 2 of the Regulations. Expert advisors must be qualified to teach the subject for which they are certified. For Area I, holders of the Certificate “Biometrics in Medicine“ are qualified to serve as such expert advisors.

Competence in complementary fields can be acquired in special courses. Contact addresses for information on such courses is provided by the Societies at the following Web sites:

GMDS: http://www.gmds.de
IBS-DR: http://www.biometrische-gesellschaft.de

3. Recognition of Qualifications

University graduates may apply directly to the Certifying Committee “Biometrics in Medicine“ as provided in § 2, Section 2 or § 2, Section 3 if the practical experience and specialized qualifications are documented as specified in Part 2 above.

Candidates qualified according to § 2 of the Regulations with a non-medical degree who also have completed a doctorate in medicine are considered competent in the fields of Part 2, Area II.

Postgraduate courses of study may be recognized as qualifications according to § 2, Section 2. Applications for recognition of such qualifications are to be made by the director of these courses of studies directly to the presidents of the Societies. Recognition of competence based on such qualifications must conform with the list of topics given in Areas I to III in Part 2 above.

4. Application Procedure

Applications for the Certificate “Biometrics in Medicine“ according to § 4 of the Regulations may be sent at any time to the chair of the Certification Committee. The current chair is

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The application must include the following documents:

a) Curriculum vitae
b) Proof of the university degree according to § 2 of the Regulations
c) Proof of five years’ practical experience according to § 2, Section 1, Number 3 of the Regulations and Part 2, Items a-g of the Appendix.
d) Description of courses of advanced study according to § 2, Section 1, Number 4 of the Regulations and Part 2, Areas I through III of the Appendix. The areas of competence should be made explicit in the report.
e) The advisor’s evaluation of the candidate’s competence in complementary areas.
f) Lists of scientific papers presented and publications, including unpublished work if appropriate. The lists should be thematically structured according to the fields of specialization given in Part 2 of the Appendix.
g) A maximum of three offprints of major publications or a corresponding number of unpublished reports or presentations.
h) Proof of payment of the application fee to the GMDS in accordance with § 4, Section 3 of the Regulations. Currently this fee is in the amount of
   100,-- €
   to be paid to the
   Deutsche Apotheker- und Ärztebank e.G. Cologne, Germany
   Account-Number 000 160 1822
   Bank Code: 370 606 15
i) Three proposed topics for the oral conference according to § 6 of the Regulations. These topics should be clearly interdisciplinary and relevant to practical and methodological problems of clinical studies.