Danish Society for Biopharmaceutical Statistics

Anniversary event

DSBS 25 years

31 March 2017 at Kollekolle, Værløse

Karsten Schmidt, Claus Bay & Merete Jørgensen:

Biostatistics in the regulatory environment and the formation of DSBS in the 1990's

Karsten part 1

Milestones prior to DSBS

1991	**Committee on Proprietary Medicinal Products CPMP issued a Good Clinical Practice (GCP) guideline mentioning the use of statistics**
1991	Paper on Statistics and Statisticians in Drug Regulation in UK in Journal of the Royal Statistical Society
1991	Formation of the ISCB working party on Statistics in European Drug Regulation (SEDREG)
1991	Formation of the European Federation of Statisticians in the Pharmaceutical Industry (EFSPI)
1992	Formation of the Danish Society for Biopharmaceutical Statistics (DSBS)

Claus part 1

Løvens Kemiske Fabrik
Industriparken 55
2750 Ballerup
Claus Bay

19/02/1992
MerJ/ab

Novo Nordisk

Novo Nordi
Niels Steensen
2820 Gentofte
Denmark
Tel. 4443 8033
Fax 3168 2568
Telex 15031
A/S reg. nr. 162

Til din og relevante medarbejderes orientering

Der indkaldes til stiftende generalforsamling i Dansk Selskab for Biofarmaceutisk Statistik.

Generalforsamlingen afholdes den 5. marts 1992 kl. 17.00 på

Domus Hagedorn, Novo Nordisk A/S
Niels Steensensvej 4
2820 Gentofte

Findes lettest ved indgang gennem den lille låge på Niels Steensensvej (overfor Novo Nordisk Biopharmaceuticals Division), stien munder ud ved Domus Hagedorn.

Dagsorden for mødet vil være:

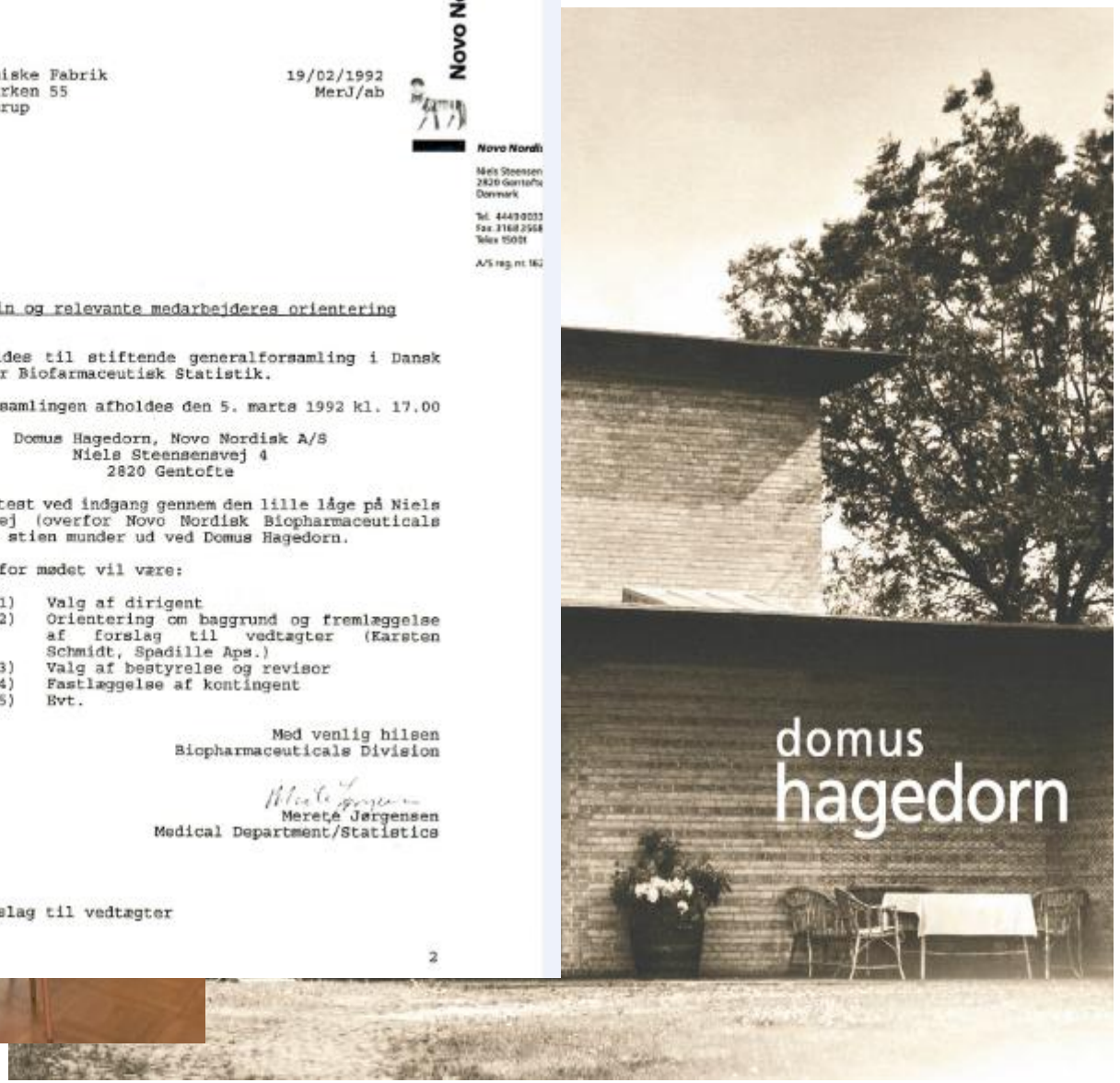
1) Valg af dirigent
2) Orientering om baggrund og fremlæggelse af forslag til vedtægter (Karsten Schmidt, Spadille Aps.)
3) Valg af bestyrelse og revisor
4) Fastlæggelse af kontingent
5) Evt.

Med venlig hilsen
Biopharmaceuticals Division

Merete Jørgensen
Medical Department/Statistics

Bilag: Forslag til vedtægter

2



DSBS

Dansk Selskab for Biofarmaceutisk Statistik

c/o Merete Jørgensen
Novo Nordisk A/S
Niels Steensens Vej 1
DK-2820 Gentofte, Danmark
Tlf.: (+45) 44 44 88 88
Fax: (+45) 31 68 35 68

Meddelelse om DSBS
Brev 27. marts 1992

27. marts 1992

Meddelelse om

Nyt selskab for biofarmaceutisk statistik

Dansk Selskab for Biofarmaceutisk Statistik (DSBS) blev stiftet ved en generalforsamling den 5. marts 1992. Selskabets formål er at fremme udveksling af information mellem fagstatistikere, som arbejder for den farmaceutiske industri i og udenfor Danmark, samt at virke for højnelsen af den faglige standard og at fremtræde udadtil som sagkyndig.

Selskabet vil medvirke til øget internationalt samarbejde på områder, der vedrører biofarmaceutisk statistik.

Som medlemmer kan optages personer, som primært arbejder som fagstatistikere i eller for den farmaceutiske industri med den ekstra klausul, at firmaet samtidig er firmamedlem.

Ved selskabets stiftelse tilmeldtes 22 medlemmer fra 6 forskellige danske virksomheder, som beskæftiger fagstatistikere arbejdende med biofarmaceutisk statistik.

Bestyrelsen består af:

Claus Bay, Løvens Kemiske Fabrik A/S (kasserer)
Merete Jørgensen, Novo Nordisk A/S (sekretær)
Karsten Schmidt, Spadille Biostatistik ApS (formand)

Med venlig hilsen

Karsten Schmidt

DSBS Dansk Selskab for Biofarmaceutisk Statistik

c/o Merete Jørgensen
Novo Nordisk A/S
Niels Steensens Vej 1
DK-2820 Gentofte, Danmark
Tlf.: (+45) 44 44 88 88
Fax: (+45) 31 68 35 68

DSBS medlemsliste pr 30/4 1993

Aage Vølund, Novo Nordisk A/S
Philip Hougaard, Novo Nordisk A/S
Torben Koustrup Sørensen, Novo Nordisk A/S
Carl Bilbo, Novo Nordisk A/S
Ingrid Sofie Dengsøe, Novo Nordisk A/S
Gert Nielsen, Novo Nordisk A/S
Merete Jørgensen, Novo Nordisk A/S
Sigrid Jensen, Novo Nordisk A/S
Bjarne Nielsen, Novo Nordisk A/S
Henrik Løft Jacobsen, Novo Nordisk A/S
David Edwards, Novo Nordisk A/S
Jesper Wittenburg, Spadille Aps
Karsten Schmidt, Spadille Aps
Søren Pedersen, Løvens kemiske Fabrik
Signe Birk Jensen, Løvens kemiske Fabrik
Claus Bay, Løvens kemiske Fabrik
Susanne Møller, Løvens kemiske Fabrik
Per Tanghøj, Lundbeck A/S
Svenn Horsgård, Lundbeck A/S
Ole Lemming, Lundbeck A/S
Anders Mørup, Dumex A/S
Birgitte Nørgård Larsen, Dumex A/S
Inger Pryds Pedersen, Dumex A/S
Severin Olesen Larsen, Statens Seruminstitut
Adam Gottschau, Statens Seruminstitut
Henrik Wachmann, Statens Seruminstitut

26 members in total

DSBS

Dansk Selskab for Biofarmaceutisk Statistik

Sekretær:
Bjarne Nielsen
BioData Services ApS
Centervænget 19, 3400 Hillerød
Tlf. 48 20 15 70, Fax 48 20 15 71
E-mail: bn@biodataservices.dk

Agenda for DSBS 10-års jubilæums arrangement

Fredag den 8. november kl. 13

Mødested: Mødelokale 1

DGI Byen
Tietgensgade 65
1704 København V
Tlf. 33 29 80 00

Tidspunkt	Foredrag:	
kl. 13	Interpretation of Controversial Sections of ICH E9, E10, and the CPMP Points to Consider documents, illustrated with case studies	Dr. Robert Hemmings, Medicines Control Agency
kl. 15	Modeling & Simulation of Clinical Trials as an Instrument to Achieve Breakthrough Performance Improvements in Drug Development	Dr. Eugene Cox, Pharsight Corp.
	Socialt arrangement:	
	Riffelskydning - med flotte præmier	
kl. 19	Middag	

Merete part 1


92 8 18


92 8 18

10/03/1996

DIA Workshop on Statistical Methodology in Clinical Research & Development

Copenhagen April 1996

20/08/2000

2nd International Workshop on Statistical Methodology in Non-Clinical R&D

Montreux September 2000

25/10/1999

DIA Workshop on New ICH Guideline on Choice of Control Group in Clinical Trials

The Key Statistical Issues | Brussels November 1999

01/07/1993

Presentation on

Florence August 19

10/07/1999

ISI 52th session in Helsinki, incl. EFSPI presentations

Helsinki August 1999

31/10/1998

1st International Workshop on Statistical Methodology in Non-Clinical R&D

Nice November 1998

20/09/1997

DIA Workshop on New ICH Guideline on Statistical Principles for Clinical Trials

Nice October 1997

Drug Information Association

Workshop Informal Dinner

Tuesday, November 17, 1998

19h30

in the heart of the city of Nice, and within a walking distance (ca. 30-45 minutes) of the Hotel LE MERIDIEN.

This is an optional event and is not included in the registration fee. Tickets

à FRF 200.-/Person (unlimited beverage included)

must be purchased from the DIA registration desk by the end of the afternoon coffee-break on Monday, November 16, 1998.

For Participants who are not familiar with these events, they will find an excellent opportunity to meet their colleagues in a relaxed atmosphere, and a chance to develop new professional contacts.

Please note that the Menu includes all the drinks.

PRESIDENTS OF EFSPI

Alec Vardy

United Kingdom

1990 - 1992

Andreas Zipfel

France

1992 - 1994

Karsten Schmidt

Denmark

1994 - 1996

Mick Godley

United Kingdom

1996 - 1997

Bernhard Huitfeldt

Sweden

1997 - 1999

Paul Koopman

The Netherlands

1999 - 2001

David Morgan

United Kingdom

2001 - 2003

Merete Jörgensen

Denmark

2003 - 2005

Karsten part 2

The following is a free translation and a brief summary of 2 replies in *Ugebrevet Danske Erhverv, 1993*:

Manager of the Licensing Department of Leo Pharmaceutical Products, is of the opinion that the need for employing biostatisticians at the Danish National Board of Health is not so pronounced.

In the Danish National Board of Health, the head of the Licensing Secretariat is of the opinion that the non-employment of biostatisticians is not a critical issue as persons from other areas are qualified to evaluate whether statistical requirements for clinical trials are fulfilled.

Milestones post DSBS

1994	**CPMP Note for guidance on statistical methodology in clinical trials**
1994	John Lewis employed as the first statistician in Medicines Control Agency (MCA)
1995	Formation of EMEA (later EMA) The European Agency for the Evaluation of Medicinal Products
1995	ICH E6 on Good Clinical practice in Step 4
1995	ICH3 meeting in Yokohama
1995	Formation of the ICH working group for E9 on Statistical Principles for Clinical Trials
1996	ICH E3 on Structure and Content of Clinical Study Reports in Step 4
1998	ICH E9 on Statistical Principles for Clinical Trials in Step 4
2001	ICH E10 on Choice of control groups in Clinical Trials in Step 4

International Conference on Pharmaceutical Medicine
Boston May 1998
Symposium on:

Statistics in International Harmonization

The Industry/CRO Perspective

Karsten Schmidt
CEO, Spadille ApS
Fredensborg, Denmark
Chairman of the EFSPI Working Group on E9

The European Federation of Statistician in the Pharmaceutical Industry (EFSPI) and the European Federation of Pharmaceutical Industries Associations (EFPIA) proposed changes to the ICH E3 guideline on Structure and Content of Clinical Study Reports.

- These proposals were not considered seriously enough.

It is a well-known decision theoretical fact that:

- Sometimes the only feasible compromise will be one that everybody dislikes instead of one that some love and others hate.

Claus part 2

EFSPI WORKING PARTY ON QUALIFIED STATISTICIAN

NAME TEL: (FAX:)	COMPANY
CHAIRMAN: David Morgan 01734 771977 (01734 779100)	Marion Merrell Dow Reading Road, Winnersh Berks, UK, RG11 5HQ
Claus Bay 45 44 92 38 00 (45 44 94 40 76)	Leo Pharm Products Ltd A/S Industriparken 55 DK-2750 Ballerup, Denmark
Prof H Trampisch 49 234 7 00 77 90 (49 234 70 94 3 25)	Ruhr-Universitat Bochum Hausanschrift: Overbergstr 17 D-44801 Bochum, Germany
Bernhard Huitfeldt 46 8 553 260 00 (46 8 553 28884)	Astra Arcus AB S-151 85 Södertälje Sweden
Peter van Ewijk 31 2940 79138 (31 2940 10571)	Solvay Duphar PO Box 900, 1380 DA WEESP The Netherlands
E Cobo 343 291 34 23 (343 291 35 32)	Lab Almirall SA c/Cardener, 68-74 08024 Barcelona, Spain
P Morse 0483 574949 (0483 60492)	Scotia Pharmaceuticals Ltd Woodbridge Meadows Guildford, UK, GU1 1BA

Drug Information Journal, Vol. 33, pp. 407–415, 1999

0092-8615/99

QUALIFIED STATISTICIANS IN THE EUROPEAN PHARMACEUTICAL INDUSTRY: REPORT OF A EUROPEAN FEDERATION OF STATISTICIANS IN THE PHARMACEUTICAL INDUSTRY (EFSPI) WORKING GROUP

EFSPI WORKING GROUP,* Isleworth, United Kingdom

Merete part 2

Visions on the role of Statisticians in the Pharmaceutical Industry

Merete Jørgensen
President EFSPI
VP Biostatistics, Novo Nordisk A/S

Vision & Mission

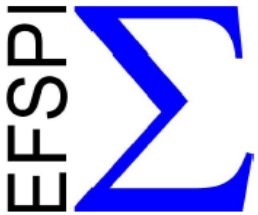
Mission:

To ensure our statistical competencies are utilised in the best way to create value in our industry

Vision:

To provide statistical competencies in an entrepreneurial and proactive way to all areas of the industry in which it will contribute to value creation

ref: Marquardt (1987)



spadille BIOSTATISTIK ApS

N.W. GADESVEJ 4, DK-3480 FREDENSBORG, BOX 25, TLF. +45 42 28 41 00, FAX +45 42 28 42 00, GIRO 8 99 80 43

TELEFAX to: 0091 301 443-9279

Date: 1993.04.16
Ref. No.: K 113.01
Total page(s): 3

Dr. Satya D. Dubey,
Chief, Statistical Evaluation and Research Branch, HFD-713
Division of Biometrics
Food and Drug Administration
5600 Fishers Lane, Room 18B45
Rockville
MD 20857, U.S.A.

Network and working together is opening doors

Dear Satya,

I hereby fax you the paper I sent to the *49th Session of the International Statistical Institute*.

As I told you yesterday, I have not been able to really make the paper I wanted to, because the EC statistical guidelines have not been released for comments by the CPMP. Therefore, my paper expresses my intentions for what to present only. I might be forced to even do otherwise than intended if the CPMP delays the release of the guidelines. However, right now I expect the guidelines to be released after the next CPMP meeting in May.

If you have any idea of the date at which the session on harmonization takes place, please let me know.

I shall keep in touch with you and look forward to meeting you again in Florence.

Best regards,

Karsten Schmidt

AN APPRAISAL OF THE PROPOSED STATISTICAL GUIDELINES FOR DRUG LICENSE APPLICATION IN THE EC

Karsten Schmidt
President, Spadille Biostatistik ApS
EFSPI Council Member
N.W. Gadesvej 4, DK-3480 Fredensborg, Denmark

The European Community Good Clinical Practice (GCP) Guidelines came into force in July 1991. These guidelines emphasize the necessity of experienced and appropriately qualified statisticians being involved in clinical trials in order to assure high quality allowing for an efficient and fast new drug approval process. However, the GCP guidelines do not give details as regards statistical methodology, and therefore preparation of a supplementary statistical guideline was initiated at the beginning of 1992. A proposal: "Guideline on