BREV
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Næste nummer af "MEDDELELSER" udkommer 3. marts 2008.
Bidrag skal være redaktøren i hænde senest **den 22. februar kl. 12.00.**

# MEDDELELSER

Dansk Selskab for Teoretisk Statistik

## Generalforsamling i DSTS

## Tirsdag 26. februar 2008, kl. 17.00
## H.C. Ørsted Instituttet, Aud. 10,
## Universitetsparken 5, 2100 København Ø

Dagsorden og beretning inde i bladet. Efter generalforsamlingen kl. ca. 17.15 er der:

**Foredrag i selskabet**

**Marc Andersen, mastat.dk**
**Udfordringerne for statistikere i pharma- og biotekindustrien**

Efter foredraget vil der være middag på "en restaurant i nærheden". Tilmelding til næstformanden (nfmd@dsts.dk), senest tirsdag den 19. februar 2008.

**Inde i bladet:**



33. årgang nr. 1 Januar 2008

**Meddelelser** er medlemsblad for Dansk Selskab for Teoretisk Statistik (DSTS), se Http://www.dsts.dk.

Selskabets formål er at fremme den statistiske videnskab og dens anvendelser.

Indmeldelse og adresseændring i DSTS gøres via http://www.dsts.dk/da/index.html.

Selskabet har en elektronisk nyhedsliste E-Meddelelser, se http://www.dsts.dk/da/index.htm.

Bidrag og stillingsopslag til Meddelelser sendes til redaktøren - red@dsts.dk. Bidrag i elektronisk form modtages helst i PDF format med sidestørrelse A4, egnet til tryk i A5 format. Alternative modtages Word, PDF, HTML eller ASCII.

Annoncering af stillingsopslag i Meddelelser koster kr. 500,- pr. side. Opgiv venligst faktureringsoplysninger. Indstik til udsendelse i konvolut sammen med Meddelelser koster kr. 2.500,- pr. standard A4 side.

Meddelelser udkommer 9 gange om året, den første mandag i måneden undtagen januar, juli og august måned.

Udgivelsesplan for Meddelelser 2008

| Nr. | Bidrag senest | Udkommer |
|---|---|---|
| 1 | 25. januar | 4. februar |
| 2 | 22. februar | 3. marts |
| 3 | 28. marts | 7. april |
| 4 | 25. april | 5. maj |
| 5 | 23. maj | 2. juni |
| 6 | 22. august | 1. september |
| 7 | 26. september | 6. oktober |
| 8 | 24. oktober | 3. november |
| 9 | 21. november | 1. december |


# Generalforsamling i DSTS
## Tirsdag 26. februar 2008, kl. 17.00
## H.C. Ørsted Instituttet, Aud. 10,
## Universitetsparken 5, 2100 København Ø

**DAGSORDEN:**

1. Valg af dirigent.

2. Bestyrelsens beretning for 2007 fremlægges til godkendelse.

3. Regnskabet for 2007 fremlægges til godkendelse.

4. Valg af medlemmer til bestyrelsen
   På valg er: Niels Richard Hansen og Marc Andersen. Jørgen Holm Petersen har siddet i to perioder og kan ikke genvælges. Bestyrelsen foreslår, at Niels Richard Hansen og Marc Andersen genvælges og at Klaus Kaae Andersen nyvælges.

5. Valg af revisor
   Bestyrelsen foreslår, at Jens Lund genvælges.

6. Behandling af fremsendte forslag.

7. Fastsættelse af næste års kontingent.
   Bestyrelsen foreslår at kontingentet fastholdes på 200 kr. (100 kr. for studerende og pensionister).

8. Eventuelt

Forslag til punkterne 4, 5 og 7 fremsendes til formanden Jørgen Holm Petersen, Biostatistisk Afdeling, Københavns Universitet, Øster Farimagsgade 5, Opgang B, Postboks 2099, 1014 København K, så han har dem i hænde senest den 11. februar 2008. Beretning udsendes snarest over E-meddelelser.

## Foredrag i selskabet

## Tirsdag 26. februar 2008, kl. 17.15
## H.C. Ørsted Instituttet, Aud. 10,
## Universitetsparken 5, 2100 København Ø

## Udfordringerne for statistikere i pharma- og biotekindustrien
**Marc Andersen, mastat.dk**

Pharma og biotek er store aftagere af statistikere, og udfordringerne er mangfoldige. For eksempel:

- I et randomiseret dobbeltblindet klinisk forsøg sammenlignes eksperimentel og eksisterende behandling. Behandlingseffekten afhænger måske af faktorer så som køn eller sygdomsstadie, men hvordan kan/skal dette indgå i a) dimensionering af forsøget, b) analyse og c) rapportering?

- Hvor specifikt er det muligt at beskrive en statistisk analyse uden at analysere data? Hvor detaileret skal kovariansstrukturen for eksempel specificeres i en mixed model?

- Hvordan behandles oplysninger/data på tværs af studier, både med hensyn til effekt og sikkerhed?

I foredraget vil jeg beskrive problemstillingerne og den overordnede ramme for udvikling af lægemidler (1), og lægge op til en diskussion af samspillet mellem (offentlig finansieret) metodeudvikling og anvendelse i industrien.

1: John A. Lewis: Statistical principles for clinical trials (ICH E9): an introductory note on an international guideline. Statistics in Medicine, 18(15), 1903-1942.

**Biostatistisk Afdeling**
**Københavns Universitet**

21. januar 2008
J.nr. 241-0002/07

**Seminarer i anvendt statistik**

Seminarerne afholdes på det gamle Kommunehospital, Øster Farimagsgade 5, opgang B. Der serveres te i Biostatistisk Afdelings bibliotek (opgang B, 2. sal) en halv time før.

**Mandag d. 4. februar 2008. kl. 15.15. lokale 5.1.16.**

**Ulf Strömberg**
**Department of Occupational and Environmental Medicine, Lund University Hospital, Sweden**

**Prioritization approaches for genome-wide association scan signals.**

Genome-wide association studies (GWAS) have in the last year led to the identification of several robustly replicating complex disease genes; primarily selected for follow-up on the basis of their high statistical significance. I here address the topical question of how best to distinguish false from true positives further down the observed distribution of association signals, by comparing three types of empirical association signals: test-based (*P*-values, Bayes factors) and estimation-based (probabilities of marked effect size after semi-Bayes adjustments).

**Onsdag d. 6. februar 2008. kl. 14.15. lokale 5.1.16 (bemærk ugedag og tidspunkt).**

**Clarice R. Weinberg**
**National Institute of Environmental Health Sciences, USA**

**Can they represent effect modification?**

In etiologic epidemiology, inference regarding potential causal effects of a factor can depend on choosing a valid model for adjustment of confounders. Classical rules for inclusion of covariates have recently been recognized as prone to error, and recent thinking has made use instead of directed acyclic graphs (DAGs). While DAGs can be extremely useful for this purpose, they do not offer any obvious way to represent effect modification, which can limit their usefulness in considering joint causal effects of multiple factors. An extension of the DAG approach is proposed, which allows for causal arrows to end at other causal arrows, following application of a specified definition for independent causal effects. Certain scenarios will be presented to illustrate the approach, under both scale dependency and scale independence, and I argue its possible superiority to the usual DAG.

**VEND!**

**Mandag d. 18. februar 2008. kl. 15.15. lokale 5.1.16.**

**Søren Rasmussen**
**Statens Institut for Folkesundhed, København**

**Use of the case-crossover design in analyses using administrative databases**

Although not considered 'the gold standard' observational studies using administrative data are important in analysing the effectiveness of the health care system, in analysing the risk of rare events and in analysing the long-term follow-up. However, proper adjustment between exposure groups can be ineffective (confounding) in administrative data due to lack of covariates with high predictive values as, for example, clinical variables. There has been mounting interest in using the administrative medical databases to study potential adverse effects of different medical therapeutics. This has created the need to develop accurate and efficient methods which try to eliminate the susceptibility to coufounding. For this reason the development of the case-crossover study has been a major advancement. The case-crossover design was originally intended to study the effects of transient exposures on the risk of acute illness. Only cases are needed by the design, since each case serves as its own control by choosing appropriate case and control time windows where exposure information is compared. Because cases are self-matched, control selection bias, study inefficency and bias by coufounding are all reduced. The background for the design and an example are presented. The example shows analyses for patients discharged for acute myocardial infarction, who use non steroidal anti-inflammatory drugs (NSAID) and the association with death and recurrent acute myocardial infarction The results are compared with other methods of adjustment for confounding.

**Mandag d. 25. februar 2008. kl. 15.15. lokale 5.1.34.**

**Friedrich Leisch**
**Ludwig-Maximilians-Universität, Tyskland**

**Finite mixtures of generalized linear regression models**

This talk introduces a very general class of finite mixtures using generalized linear regression models as components. The dependent variable can have any member of the exponential family (Gaussian, binomial, multinomial, Poisson, ...) as distribution, the regression part models the location parameter of the response. Models with varying and fixed effects allow some parameters to be fixed over a pre-specified subset of components. We also give sufficient conditions for identifiability of parameters, and show how noise components with fixed location and scale parameters can efficiently model outliers in the data. After the more formal theoretical discussion of the model class we present our implementation in R extension package flexmix, show its usage on several examples and how bootstrapping can help to diagnose identifiability problems in practice.

Per Kragh Andersen

**PRELIMINARY ANNOUNCEMENT**

***Danish Graduate Schools in Public Health Science and in Biostatistics***

**Course title: Mediation – intermediate variables, direct and indirect effects in epidemiology**

**Purpose and contents:** In observational epidemiology much energy is being spent on control of confounding, while until recently, the equally important problem of intermediate variables has largely been considered important but intractable. During the last decade or so, however, this area has come into focus in methodological research in biostatistics and epidemiology, and the purpose of this course is to present the concepts of mediation, direct and indirect effects for Danish Ph.D.students and other interested researchers in epidemiology and biostatistics. Emphasis will be on concrete methods as well as an up-to-date survey of current status in the area. Computer demonstrations will be included.

**Participants:** Ph.D.students and other interested researchers in epidemiology and biostatistics. Experience in statistical analysis of epidemiological data necessary. Max. 40 participants.

**Form:** 2+3 days full of lectures and computer demonstrations.

**Language:** English

**Course material:** A full set of slides will be provided. The course will be based on current papers, and a full reading list will be available ahead of the course. To give a taste, see e.g.

Ditlevsen S, Christensen U, Lynch J, Damsgaard MT, Keiding N. The mediation proportion: a structural equation approach for estimating the proportion of exposure effect on outcome explained by an intermediate variable. *Epidemiology* 2005;**16**:114-20.

MacKinnon DP, Lockwood CM, Brown CH, Wang W, Hoffman M. The intermediate endpoint effect in logistic and probit regression. *Clin Trials* 2007;**4**:499-513.

Pearl J. Direct and indirect effects. In: *Proceedings of the Seventeenth Conference on Uncertainty in Artificial Intelligence.* San Francisco: Morgan Kaufman; 2001:411-420.

Petersen ML, Sinisi SE, van der Laan MJ. Estimation of direct causal effects. *Epidemiology* 2006;**17:**276-284.

**Course director**: Professor Niels Keiding, Institute of Public Health, University of Copenhagen.

**Teachers:** Dr. Stijn Vansteelandt, Gent University, Belgium. Lektor Svend Kreiner, Professor Niels Keiding, Professor Finn Diderichsen, all Institute of Public Health, University of Copenhagen. Laust Mortensen, National Institute of Public Health.

**Time:** 10-11 and 28-30 April 2008 from 9-16.

**Place:** University of Copenhagen, Centre for Health and Society, Øster Farimagsgade 5.

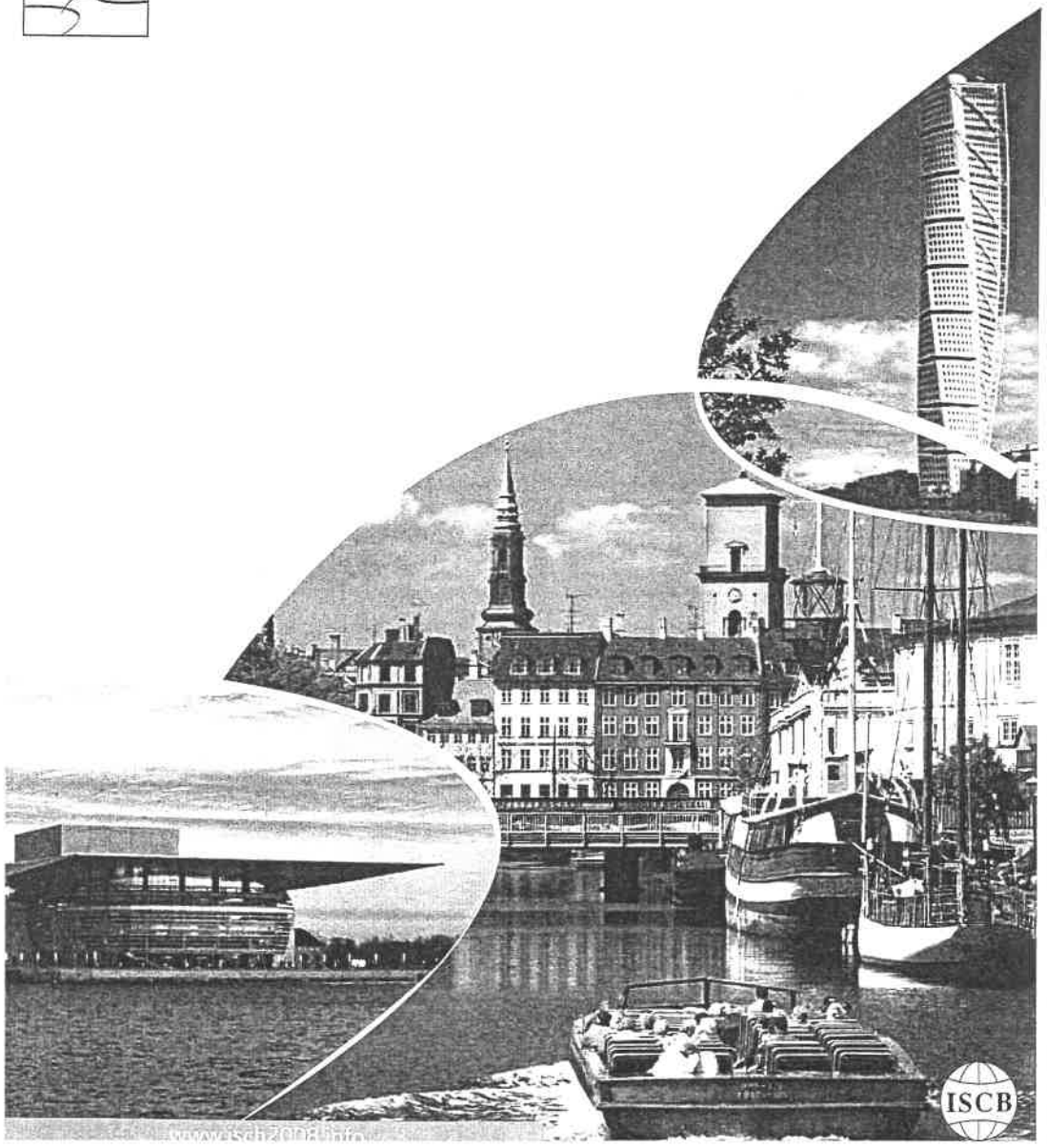
***FULL DETAILS ON REGISTRATION WILL SOON BE AVAILABLE on*** www.phdpubhealth.dk and www.phdbiostat.dk ***IF YOU WANT TO BE ALERTED WHEN THEY ARE READY, SEND A MAIL TO Lisbeth Lyng Hansen, L.L.Hansen@pubhealth.ku.dk***

# 29th Annual Conference of the International Society for Clinical Biostatistics

Second Announcement & Call for Papers

ISCB 2008

17 - 21 August 2008, Copenhagen, Denmark




www.iscb2008.info

## Invitation to Copenhagen

*On behalf of the International Society for Clinical Biostatistics (ISCB) and the Local Organising Committee, it is a great pleasure to invite you to attend the 29th Annual Conference in Copenhagen, 17-21 August 2008.*

*The Conference is held as a joint arrangement in the Øresund region (the areas of Sweden and Denmark next to the Strait of Øresund) also called Medicon Valley due to its high level of research activities within biotech and life science. The Conference logo is the bridge between Denmark and Sweden to illustrate co-operation, and because we hope that the Conference will create relations between scientists and facilitate the exchange of ideas.*

*The Conference will be held in the old buildings of the School of Architecture just behind the new Opera and on the water front opposite the Royal Palace. We are preparing an interesting scientific programme. Apart from the scientific programme you can look forward to summer in Copenhagen, an old city with character and charm, cultural events, extensive green areas - a beautiful relaxed setting for social interaction with colleagues and sightseeing.*

*We all look forward to seeing you in Wonderful Copenhagen.*

Bjarne Nielsen
Chair, Local Organising Committee

Philip Hougaard
Chair, Scientific Programme Committee

## International Society for Clinical Biostatistics

The Society was founded in 1978 to stimulate research into the principles and methodology used in the design and analysis of clinical research and to increase the relevance of statistical theory to the real world of clinical medicine.

**The 29th Annual Conference in Copenhagen** will provide a forum for the international exchange of theory, methods and applications of biostatistics in medical research and practice among clinicians, statisticians and members of other disciplines, such as epidemiologists, clinical chemists and clinical pharmacologists, working or interested in the field of clinical biostatistics.

## Committees

### ISCB Executive Committee 2008

President: Emmanuel Lesaffre
Vice President: Nobert Victor
Treasurer: Koos Zwinderman
Secretary: Harbajan H. Chadha-Boreham
Newsletter Editor: David W. Warne
Webmaster: Bjarne Nielsen
Members: Adriano Decarli, KyungMann Kim, Rumana Omar, Catherine Quantin, Jeno Reiczigel, Marie Reilly, Martin Schumacher, Vassiliki-Anastasia Sypsa

### Local Organising Committee

Chairman: Bjarne Nielsen
Vice Chairman: Helge Gydesen
Treasurer: Ingrid S. Harbo
Secretary: Klaus Juel Olsen
Webmaster: Judith L. Jacobsen
Members: Per Broberg, Esben Budtz-Jørgensen, Philip Hougaard, Elisabeth Svensson

### Scientific Programme Committee

Chairman: Philip Hougaard (Denmark)
Members:
Michal Abrahamowicz (Canada)
Antonella Bacchieri (Italy)
Peter Bauer (Austria)
Carl-Fredrik Burman (Sweden)
Saskia Le Cessie (The Netherlands)
Simon Day (UK)
Susanne Ditlevsen (Denmark)
Amita Manatunga (USA)
Martin Schumacher (Germany)
Zdenek Valenta (Czech Republic)

# Scientific Programme

## Programme Overview

You may check the homepage for updates to the invited programme.

| | Sunday 17 August | Monday 18 August | Tuesday 19 August | Wednesday 20 August | Thursday 21 August |
|---|---|---|---|---|---|
| 08.00 | Registration | Registration | 08.30 Registration | 08.30 Registration | Registration |
| 09.00 | Pre-conference courses | 09.20 Welcome<br>Invited session | Invited session / Contributed sessions | Invited session / Contributed sessions | Mini-Symposium 1* / Mini-Symposium 2** |
| 10.30 | Refreshments | Refreshments | Refreshments | Refreshments | 10.45 Refreshments |
| 11.00 | Pre-conference courses | Invited session / Contributed sessions | Invited session / Contributed sessions | Keynote lecture | 11.15 Mini-Symposium 1* / Mini-Symposium 2** |
| 12.00 | | | | 12.00-13.00 Annual General Meeting | |
| 12.30 | | Lunch | Lunch | | |
| 12.45 | Lunch | | | 13.00 Lunch | |
| 13.45 | Pre-conference courses | | Conference Excursions | | ISCB 2008 / ISCB |
| 14.00 | | Contributed sessions | | Contributed sessions | |
| 15.30 | Refreshments | Refreshments | | Refreshments | |
| 16.00 | Pre-conference courses | Invited session / Contributed sessions | | Contributed sessions | |
| 17.30 | | | | | |
| 18.00+ | | 19.00-20.30* Welcome reception at Copenhagen City Hall | | 19.30- Conference dinner at Restaurant Paafuglen | |
| All day | | Poster Session | Poster Session | Poster Session | |

*) Venue of Mini-symposium 1: Conference venue - The School of Architecture.
**) Venue of Mini-symposium 2: H. Lundbeck A/S, Ottiliavej 9, Copenhagen Valby.
There will be bus shuttle from Copenhagen Central Station to H. Lundbeck in the morning and to Copenhagen Central Station at 13:00 hrs.

## Important Dates

| | |
|---|---|
| 1 March 2008 | Deadline for submission of abstracts and Conference Awards applications |
| 1 May 2008 | Notification of abstract acceptance |
| 1 June 2008 | Final date for low registration fee |
| 17 – 21 August 2008 | Conference dates |

# Pre-Conference Courses

**Running on Sunday August 17, 2008**

### Course 1 (full day): Adaptive designs

**Presenter:** *Chris Jennison (University of Bath, UK)*

There has been much recent interest in methods to modify the design of a clinical trial at an interim stage, responding to external factors or to data observed in the study itself. We review the benefits and drawbacks of adaptive designs from both practical and theoretical viewpoints.

We shall present statistical methodology in the unifying framework of combination tests, whereby conditional Type I error is maintained at each adaptation. The first application of these methods is in sample size re-estimation, either to handle a nuisance parameter affecting sample size or to increase the power based on interim estimates of effect size. Here, it is appropriate to draw comparisons with group sequential methods, which may be used to achieve similar goals.

Other uses of adaptive methods are in problems with multiple hypotheses. After reviewing methods for multiple testing with protection of the overall type I error probability, we shall survey applications to: Changing the treatment definition; Changing the primary endpoint; Refining the patient population; Switching between superiority and non-inferiority.

The final topic will be seamless transition from Phase II to Phase III clinical trials whereby a treatment or dose level is first selected then tested in a confirmatory stage, all within one over-arching trial design.

### Course 2 (full day): Models for discrete longitudinal data

**Presenter:** *Geert Molenberghs (Hasselt University, Belgium)*

Starting from a brief introduction on the linear mixed model for continuous longitudinal data, extensions will be formulated to model outcomes of a categorical nature, including counts and binary data. Based on Verbeke and Molenberghs (2005), several families of models will be discussed and compared, from an interpretational as well as computational point of view. First, models will be discussed for the full marginal distribution of the outcome vector. Such models allow inference to be based on maximum likelihood principles, but they have the disadvantage of requiring complete specification of all higher-order interactions. Two alternatives will be discussed: random-effects models as well as semi-parametric marginal models with specification of the first moments only, or the first and second moments only. Estimation and inference will be discussed and illustrated in full detail, and it will be extensively argued that both approaches yield parameters with completely different interpretations. Finally, when analyzing longitudinal data, one is often confronted with missing observations. It will be shown that, if no appropriate measures are taken, missing data can cause seriously biased results, and interpretational difficulties. Methods to properly analyze incomplete data, under flexible assumptions, are presented. Key concepts of sensitivity analysis are introduced.

### Course 3 (half day, morning): Bayesian methods for biostatistical applications

**Presenter:** *Paul Gustafson (University of British Columbia, Canada)*

Following a general overview, certain aspects of the Bayesian approach will be emphasized. To considerable extent the focus will be on concepts and modelling issues, rather than on technical and computational issues. One emphasis will be on Bayesian methods applied to deal with various limitations often arising with data in biostatistical contexts, particularly in non-randomized studies. Such limitations include poorly measured variables, unobserved confounders, and selection bias. Another emphasis will be on the use of the Bayesian paradigm to make modelling assumptions less rigid. The idea here is that prior distributions can reflect the notion that key modelling assumptions are only approximately correct rather than exactly correct. Examples will be drawn from a variety of health research contexts.

### Course 4 (half day, afternoon): Non-inferiority trials

**Presenters:** *Simon Day (Roche, UK) and Nicole Close (US Army Medical Research and Materiel Command, USA)*

This course gives an overview of many of the issues faced by those designing, running, analysing, presenting and interpreting studies aimed at showing that a new therapy is 'no worse than' (from a practical point of view) an existing therapy. The presentation will be at a very practical level but requires, as a pre-requisite, a good level of understanding of the fundamental principles of clinical trials. The course is relevant to those in the pharmaceutical sector as well as those from government and academia; it will include scientific and regulatory issues, with examples taken from the US and Europe.

At the end of the course, attendees should understand the purpose and potential benefits of non-inferiority studies and how they differ from superiority studies. Attendees should also understand the extra difficulties associated with these types of studies, over and above those of superiority studies.

# Invited Sessions

**Invited sessions on August 18-20, 2008**

### President's invited lecture
*Niels Keiding* (University of Copenhagen, Denmark): "Sampling patterns in event history analysis with applications to epidemiology"
Abstract: Event history models are now a well-established tool in epidemiology and demography, but the concrete statistical analysis still presents methodological challenges. Main reasons for this are the desire to involve several time origins (calendar time, age and duration) and complex sampling patterns, be it interval censoring or sampling at a cross-section in calendar time. This talk will present a framework for handling these problems in applied event history analysis as well as concrete examples, including design and analysis of time-to pregnancy data as well as follow-up studies of fillings in primary teeth.

### Opening plenary session: State-of-the-art lectures
*Susan Ellenberg* (University of Pennsylvania, USA) "Data Monitoring in Clinical Trials: Controversies and Conundrums"
David Clayton (University of Cambridge, UK) "Genetic epidemiology after genome-wide association studies"

### Causal models and evidence from non-randomised studies
*Miguel Hernan* (Harvard University, USA) "Observational studies analyzed like randomized experiments: the case of postmenopausal hormone therapy and heart disease"
Stijn Vansteelandt (Ghent University, Belgium) "Modeling and estimating direct effects"
Betty Kirkwood (London School of Hygiene and Tropical Medicine, UK) Title to be announced

### Recent developments in genetics
*Juni Palmgren* (University of Stockholm, Sweden) "Models for genetic linkage and association based on family data"
Jelle Goeman (Leiden University Medical Center, Netherlands) "Testing sets of genes in gene expression studies"
One speaker to be announced. Please check the homepage for updates.

### How to analyse an adaptive trial: Tests, estimates and confidence intervals
*Werner Brannath* (University of Vienna, Austria) Title to be announced
Carl-Fredrik Burman (AstraZeneca, Sweden) "Statistical philosophy and the analysis of flexible trials"
John Whitehead (Lancaster University, UK) "Sequential procedures for discovering genetic associations with adverse drug reactions, and what to do when you find one"

### Biomarkers, qualification and application
Three speakers to be announced. Please check the homepage for updates.

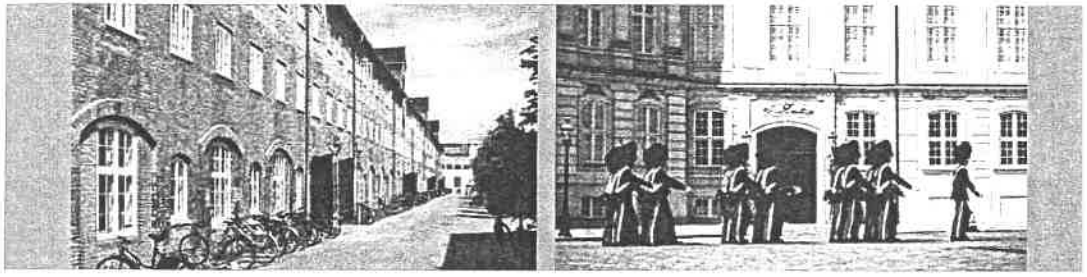
### Special session: Working places in biostatistics
A session discussing non-scientific aspects of how we organise work and describing institutions employing biostatisticians, in an international European perspective.
*Michael Branson* (Novartis, Switzerland) "The role and opportunities of statistical methodologists within pharmaceutical development"
*Niels Kamp* (Novo Nordisk, Denmark) "Challenges in outsourcing statistical tasks"
*Saskia Le Cessie* (Leiden University Medical Center, Netherlands) "Working with doctors in a hospital"
*Antonella Bacchieri* (Sigma-tau, Italy) "Which qualifications are needed to get a job as biostatistician in the pharmaceutical industry"
*Carmen Maria Cadarso Suarez* (University of Santiago de Compostela, Spain) "Life at a university" (tentative title)
*Colin Neate* (Roche, UK) "The significance of clinical statisticians in the pharmaceutical industry"

# Mini-symposia

This year there will be two mini-symposia running on August 21, 2008. Be sure to mark which mini-symposia will be participate in, as they will take place two different places in Copenhagen, so switching between them will not be possible.

### Mini-symposium 1: Recent developments in survival data
This will take place at the conference venue.

### Recurrent events:
*Per Kragh Andersen* (University of Copenhagen, Denmark) "Intensity-based models for recurrent events".
Richard Cook (University of Waterloo, Canada) "Estimation of marginal features of recurrent event processes under event-dependent censoring".



### Considering survival times as first hitting times:
*Odd Aalen* (University of Oslo, Norway) Title to be announced.

### Register-based studies:
*Preben Bo Mortensen* (University of Aarhus, Denmark) Title to be announced
*Marie Reilly* (University of Stockholm, Sweden) "Timing and duration of familial breast cancer risk, using population register data"
*Bianca de Stavola* (London School of Hygiene and Tropical Medicine, UK) "Sensible uses of linked registry data when either outcome or exposure data are missing"

### Mini-symposium 2: Design of phase I and II studies
This will take place at H. Lundbeck A/S in Valby and contain talks on the following three topics:

### Phase I studies: Dose-escalation
*Stephen Senn* (University of Glasgow, UK) "Dose-finding in first-in man studies in healthy volunteers"
*Deborah Ashby* (University of London, UK) Title to be announced

### Phase II studies: Proof of concept
*Michael Branson* (Novartis, Switzerland) "Proof of concept: The translational step from drug discovery to the clinic"
*Andy Grieve* (King's College, UK) Title to be announced

### Phase II studies: Dose-finding. Choosing doses before the study as well as choosing doses after the study
*Frank Bretz* (Novartis, Switzerland) "Optimal designs for dose finding studies"
*Anders Källén* (AstraZeneca, Sweden) "Dose-response - an estimation problem"

## Call for Abstracts

Contributed papers (oral presentations as well as posters) are welcome in any area of biostatistics, epidemiology and related topics. The Scientific Programme Committee particularly encourages submission of contributed papers about the invited session topics, as well as the following topics. Papers based on the presentations at ISCB-29 may be submitted for a special conference issue of Statistics in Medicine. Abstracts will be evaluated before inclusion in programme. **Please note that presenters of abstracts are not automatically registered for the conference. Abstracts and registration for the conference are handled separately.**

### Recommended topics

- Novel approaches to the design and analysis of clinical trials
- Causal models
- Randomised versus non-randomised studies
- Application of biomarkers in clinical studies
- Adaptive clinical trials
- New developments in statistical methods for epidemiology
- Survival analysis
- Pharmaceutical statistics, including phase I and regulatory issues
- Bayesian methods
- Analysis of repeated measurements data, discrete as well as continuous
- Use of genetic data in clinical and epidemiological studies

The Scientific Committee will review all abstracts, and notification will be given by 1 May 2008. If the abstract has been accepted, an abstract number will be assigned, which should be given as reference when making any inquiries pertaining to the abstract. Accepted abstracts will be published in the Abstract Book.

All correspondence regarding the abstracts will be sent to the corresponding author. He or she will also be informed as to whether the paper has been accepted as an oral presentation or a poster presentation. Postgraduate students who apply for a student conference award may also send in a regular abstract. Student award winners automatically qualify for an oral presentation. All others will be treated as regular participants.

### GUIDELINES FOR SUBMISSION OF ABSTRACTS

**Abstracts must be submitted no later than 1 March 2008**

Abstracts can only be submitted on-line.
Please read the following guidelines carefully before submitting your abstract at www.iscb2008.info or www.ics-online.com.

1. Authors presenting abstracts must register immediately after hearing their abstract has been accepted.
2. Abstracts must be submitted in English and on the Internet at the above web sites.
3. Titles should be entered in the "Title Field" (not as part of the abstract) and should contain no more than 20 words or 70 characters including space.
4. Abstract text should be entered in the "Abstract Text Field" and should contain no more than 250 words. The system will not allow you to enter more than 250 words.
5. Any tables, graphs or diagrams should be e-mailed to abstracts@ics.dk
6. Authors' names and institutions should be entered in the appropriate fields. The following data is needed for the "Institution Field" – Name of the Institution, Department, City and Country.
7. The abstract should be informative, containing: a) a statement of the study's objectives; b) a brief statement of methods if relevant; c) a summary of the results obtained and d) a statement of the conclusions reached.
8. Please avoid references. However, if references are used, they should be included in the abstract texts as: authors, journal, year, volume, and pages.
9. Single space all text and do not leave blank lines. Use standard abbreviations. Place a special or unusual abbreviation in parenthesis after the full word the first time it appears. Use generic names of drugs and write numbers as numerals rather than words.

Abstracts, which do not conform to the above guidelines, will not be accepted.

## Information to Presenters

The auditoria will be equipped with pc with Power Point software and data projectors. You are welcome to bring your own laptop, however, please be sure to visit the technicians before your lecture, in order to ensure the right equipment is in place. There will be no possibility for slide presentation. Presenters are kindly requested to send a CD of their presentation or e-mail to the Conference Secretariat: abstracts@ics.dk



# 29th Annual Conference of the International Society for Clinical Biostatistics

**17-21 August 2008**

**Copenhagen, Denmark**

## Student Conference Awards

Student Conference Awards are available for registered postgraduate students to attend and present a paper at the 29th ISCB Meeting in Copenhagen, Denmark, during 17-21 August 2008. At least three awards will be made. Selection will be made on the basis of a summary of the paper to be presented, which should illustrate the application of statistical methodology to clinical or epidemiological research. Results of particular studies are of interest only if the analysis has methodological implications or shows a novel and interesting application of biostatistics. Applications should be sent to:

Professor KyungMann Kim
Department of Biostatistics and Medical Informatics
University of Wisconsin School of Medicine and Public Health
600 Highland Ave, K6/438 CSC
Madison, WI 57392-4675
U.S.A.
Tel: +1 608 265 6380
FAX: +1 608 265 5579
Email: kmkim@biostat.wisc.edu

For application forms and details of the selection process, please visit www.iscb2008.info. The closing date for application is 1st March 2008.

Biostatistician – International Clinical Research, H. Lundbeck A/ S

A temporary position (15 months) as biostatistician is open in the Biostatistics Department, International Clinical Research. The department works primarily within clinical research, but contributes to the entire drug development process from discovery to market across the range of therapeutic areas within psychiatry and neurology. The current staffs include 23 biostatisticians (hereof 3 in Singapore), 6 statistical programmers, 1 PhD student, and 3 technical staff members. We offer a challenging job with broad career opportunities in a dynamic and open working atmosphere with focus on personal and scientific development.

Your job
Part of your responsibility will be to provide statistical input for designing and planning of clinical studies and to participate in statistical analysis and interpretation of clinical studies in all phases of development and non-clinical safety data. You participate in preparing publications, which involves exploratory statistical analyses of a diverse range of clinical study data. You work in close collaboration with clinical researchers and other specialists, exerting your expertise in statistical methodology and keeping abreast of current practices of pharmaceutical R&D.

Your qualifications
Our preferred candidate
- holds an MSc or PhD degree in Statistics or Mathematical Sciences
- has programming experience and familiarity with statistical software
- has a strong interest in applying statistical methods to biological problems
- has an interest in clinical aspects as well as statistical aspects and in working with clinicians
- is goal-oriented, innovative, and flexible, work well under pressure, and possesses the ability to listen, be analytic and proactive
- is fluent in oral and written English
- is a team player and able to interact smoothly with colleagues and collaborators from different functional areas and/or companies

Further information
Please contact Head of Department, Ingrid Sofie Harbo, on +45 3643 2004 or Head of Section, Mette Krog Josiassen, on +45 3643 3633. We also recommend you to visit our website www.lundbeck.com.

Your application
Please submit your application electronically at http://www.lundbeck.com/careers/jobs/vacancies/default.asp, where you will find this position in the list of 'Current vacancies'. Applications must be received no later than February 25, 2008. Please state in your application where you have seen this advertisement.

cyncron

## // Cyncron søger Biostatistikere

Cyncron Biometrics A/S søger to Biostatistikere til vores kontor i Birkerød.

Er du indstillet på et engageret, serviceminded arbejde i et firma, hvor team, selvstændighed og indflydelse på jobbet er kendetegnende?
Har du erfaring som Biostatistiker indenfor kliniske afprøvninger?

I så fald kan vi tilbyde dig et spændende job i en ambitiøs konsulent-virksomhed fokuseret på kliniske afprøvninger af lægemidler.

Cyncron Biometrics arbejder indenfor Data Management og Statistik. Vi har erfarne folk indenfor begge områder. Cyncron Biometrics er en del af Cyncron koncernen, som i alt tæller ca. 70 ansatte og dækker hele spektret fra den kliniske fase I til fase IV og til safety surveillance. Cyncron Biometrics består af 20 medarbejdere, heraf 6 statistikere og 5 programmører i statistik-afdelingen.

Cyncron Biometrics tilbyder højt kvalificeret og effektiv assistance til medicinalvirksomheder og bioteknologiske virksomheder. Nogle gange skal det derfor gå særlig stærkt, og alligevel skal kvaliteten stadig være i top. Det skal du, som del af et team på tværs af faggrænser, være indstillet på. Vi kan til gengæld tilbyde et afvekslende job, hvor du får set mange forskellige typer opgaver fra forskellige firmaer.

Som person skal du være seriøs og have en god humoristisk sans. Du vil komme i kontakt med mange forskellige slags kunder, som vi forventer du servicerer på bedste vis. Du er som biostatistiker fagligt velfunderet, forstår at "tale statistik" med ikke-statistikere, og trives med dagligt at bruge dine formidlingsevner ved kontakt med klienter og i interne projektteams.

Hvis ovennævnte har vakt din interesse, er du velkommen til at kontakte Head of Statistics, Per Settergren Sørensen på telefon 45672254, eller via e-mail på PSS@cyncron.com.
Ansøgning mærket Biostatistiker stiles til: Per Settergren Sørensen, Cyncron A/S, Datavej 24, 3460 Birkerød. Du er også velkommen til at sende din ansøgning pr. e-mail.

*Cyncron (tidligere Medicon) har siden 1985 samarbejdet med lægemiddel-firmaer om udvikling af nye lægemidler, og tilbyder i dag alle elementer i afviklingen af en klinisk afprøvning i fase 1-4. Cyncron har oprettet en forskningsklinik med 60 senge sengepladser på Østerbro i København. Cyncron Biometrics tilbyder højt kvalificeret Data Management og Statistik.*
*Læs evt. mere på vor hjemmeside www.cyncron.com. Tlf. 70202058.*

## Statistiker søges

Vi har i Larix en lang række statistikopgaver indenfor klinisk forskning. Vi har brug for en ekstra statistiker med en lyst til at indgå i et lille team hvor vi arbejder godt sammen og har det rart mens vi knokler.

Vi har brug for at du

- har en matematisk statistisk uddannelse som cand. stat., ingeniør eller lignende.
- er god til mundtlig og skriftlig kommunikation – også på engelsk
- er god til at samarbejde, er nem at omgås og er serviceminded
- kan bevare overblikket i pressede situationer
- meget gerne har relevant erfaring med klinisk statistik og ICH-GCP
- meget gerne har en rimelig baggrund i SAS programmering

Vi tilbyder et spændende og udfordrende job hvor du vil komme til at arbejde med en række forskellige typer af statistiske opgaver primært ifm. kliniske studier. Eksempelvis vil du komme til at lave de statistiske analyser og afrapporteringer fra kliniske studier, skrive statistiske analyseplaner, og give input til forsøgsprotokoller inklusiv sample size beregninger. Afhængigt af din baggrund vil nogle opgaver løses hos Larix, mens andre løses som konsulent udstationeret hos kunden. Derudover tilbyder vi en konkurrence-dygtig løn med bonus og pension, efteruddannelse og fleksibilitet samt stor mulighed for at påvirke hvordan vi udvikler os fremover.

Larix er et mindre konsulent og kontraktopgavefirma. Vi er ialt 12 personer og arbejder med statistik, data management, programmering, trial management og medical writing. Langt den overvejende del af vores kunder er små eller store farmaceutiske firmaer og biotek firmaer. Vi er midt i en kraftig udvidelse af vores aktiviteter og det er derfor en spændende periode at være med i.

Hvis du er interesseret i at høre mere så ring til Klaus Juel Olsen, Head of Statistics på 61 61 80 11, kjo@larix.dk. Alternativt, send en ansøgning med CV på mail eller til Larix Aps, Bymidten 78, 3500 Værløse.

# Kalender 2008

| Dato | No. | Aktivitet |
|---|---|---|
| 26-28/2 | 9 / 07 | Ph.D course, Biostatistisk Afdeling, Københavns Universitet<br>*Machine learning tools for model building and inference* |
| 29-31/2 | 9 / 07 | Thiele Centre, Sandbjerg Estate, Sønderborg:<br>*Workshop on Stochastics in Turbulence and Finance* |
| 26/2 | 9 / 07 | DSTS: Generalforsamling, H.C. Ørsted Instituttet, Københavns Universitet |
| 26/2 | 1 / 08 | DSTS foredrag, H.C. Ørsted Instituttet, København Universitet:<br>Marc Andersen (mastat.dk): *Udfordringerne for statistikere i pharma- og biotekindustrien* |
| 4/2 | 1/08 | Biostatistisk Afdeling, Københavns Universitet<br>Ulf Strömberg (Department of Occupational and Environmental Medicine, Lund University Hospital, Sweden): *Prioritization approaches for genome-wide association scan signals* |
| 6/2 | 1/08 | Biostatistisk Afdeling, Københavns Universitet<br>Clarice R. Weinberg: National Institute of Environmental Health Sciences, USA:<br>*Can they represent effect modification?* |
| 18/2 | 1/08 | Biostatistisk Afdeling, Københavns Universitet:<br>Søren Rasmussen (Statens Institut for Folkesundhed, København): *Use of the case-crossover design in analyses using administrative databases* |
| 25/2 | 1/08 | Biostatistisk Afdeling, Københavns Universitet:<br>Friedrich Leisch (Ludwig-Maximilians-Universität, Tyskland): *Finite mixtures of generalized linear regression models* |
| 10-11/4, 28-30/4 | 1/08 | Danish Graduate Schools in Public Health Science and in Biostatistics, University of Copenhagen: *Mediation – intermediate variables, direct and indirect effects in epidemiology.* |
| 14-18/6 | 9 / 07 | Thiele Centre, Sandbjerg Estate, Sønderborg:<br>*Conference on Efficient Monte Carlo: From Variance Reduction to Combinatorial Optimization* |
| 17-21/8 | 1/08 | 29th Annual Conference of the International Society for Clinical Biostatistic, Copenhagen |

No.: Nummer af meddelelser hvor arrangement er annonceret.

# Nyt om navne

Philip Hougaard er udnævnt til Chief Specialist hos H. Lundbeck A/S som anerkendelse af betydningen af hans store bidrag til den kliniske udvikling.

Nyansættelser hos H. Lundbeck A/S: Slobodan Zdravkovic (tidligere SSI), Klaus Larsen (tidligere Hvidovre Hospital) og Rikke Stubbe Hansen (nyuddannet fra DTU).