Università
della
Svizzera
italiana

BioBusiness
BioEntrepreneurship
Life Sciences Entrepreneurship
BioClub

BioClub

BioBusiness Network at USI

"Clinical Trials Design and Management for Start-Up Companies"

LUGANO: 5-6 NOVEMBER 2012

SUPPORTED BY

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WELCOME

The BioEntrepreneurs Club (BioClub) was established in 2011 at Università della Svizzera italiana, Lugano. BioClub seeks to inspire, connect and educate BioEntrepreneurs. It brings together entrepreneurs, venture capitalists, and industry experts. The initiative consists of lectures, workshops, panel discussions on major issues towards the launch and development of a successful bioscience enterprise. This package of activities is designed to contribute to the creation of a ToolBox with which to remove barriers to innovation and take inventions to market.

Clinical trials, of each size and complexity, require efficient trial management. This workshop aims to provide an overview of how to design, conduct and analyze clinical trials. A number of highly interactive lectures connect up, and underpin, the underlying methodology with realistic examples.

Advice will be given on recommended preconditions that lead to a successful clinical development program.

I wish you a successful and stimulating BioClub meeting at Università della Svizzera italiana!

Prof. Dr. Piero Martinoli, President USI

PROGRAMME

Clinical Trials Design and Management for Start-Up Companies

Moderation: Dr. J. Staeheli

Monday

10:00	First coffee together
10:30 - 11:00	Introduction and presentation of participants
11:00	**Introduction to Drug development** - Pre-clinical research (short overview). - The phases of clinical development. - Example of a Phase I trial. - Example of a clinical development program. - The stakeholders – the patients, healthy volunteers, medical professionals, industry, regulators.
12:30 - 14:00	Lunch
14:00 - 15:30	**Clinical Trial Design, Part I** - Objectives, basic principles: blinding, randomization, stratification, the trial protocol. - Methods and designs of pre-clinical and clinical trials. - Principles of experimentation. - Pitfalls in trials with humans. - Objectives and Designs in early phase clinical trials. - "First in man", "Proof of concept" and "Proof of mechanism" trials. - Measurements and observations: clinical endpoints of efficacy, safety and surrogate endpoints.
15:30 - 16:00	Break
16:00 - 17:30	**Regulatory Affairs, Good Clinical Practice, Monitoring** - History of regulation of pharmaceuticals for human use. - US (FDA) and European Health authorities (EMA). - Overview on guidelines relevant for the development and marketing of pharmaceutical products: FDA, EMA and ICH (Int. Conf. of Harmonization). - GCP and Ethical Committees, Declaration of Helsinki. - Monitoring. - Outsourcing clinical trials and analysis to CROs.

PROGRAMME

Clinical Trials Design and Management for Start-Up Companies

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Tuesday

08:30 - 10:30	**Biostatistics: Principles and Methods** - How to deal with uncertainty, a practical experiment. - Inference and decision making. - Measures of location and variability. - Estimation and Bias. - Testing of hypotheses.
10:30 - 11:00	Break
11:00 - 12:30	**Clinical Trial Design, Part II** - Pharmacokinetics, Pharmacodynamics. - Statistical models. - Data management. - Analysis, Interpretation and Reporting of results.
12:30 - 14:00	Lunch
14:00 - 15:30	**Special Areas and Designs** - Biologics and Oncology: peculiarities and differences compared to the development of Primary Care drugs. - Adaptive designs, dose-response trials, drug titration. - Bioequivalence and drug/drug interaction trials.
15:30 - 16:00	Break
16:00 - 17:30	**Overview on phases II / III; process and prerequisites for licensing out** Discussion

LECTURERS

Dr. Roland Fisch has a PhD in Mathematics, from the University of Basel. After 6 years as an assistant lecturer at University, he joined Ciba-Geigy AG (later: Novartis), to provide statistical support to scientists in different areas, such a pharmaceuticals, agrochemicals, seeds, polymers, etc, for 13 years. He then joined CRST, a clinical research service group within the University of Turku, Finland, to act as a senior statistical consultant, for academic research as well as for pharmaceutical startup companies. After two years he re-joined Novartis Pharmaceuticals, as a senior statistical / modeling consultant. Roland's major areas of expertise include Bayesian analysis, clinical trial design/simulation, population pharmacokinetic-pharmacodynamic modeling, quantitative genetics.

Dr. Byron Jones is a Biometrical Fellow in the Statistical Methodology group at Novartis Pharma AG in Basel, Switzerland.
He obtained his PhD in Statistics from the University of Kent at Canterbury, UK, in 1980 and continued to work there as a Lecturer and Senior Lecturer in Statistics until 1994. He then left to take up the position of Professor of Medical Statistics at De Montfort University, Leicester, UK. At De Montfort he also created and managed a university company that provided expert statistical advice to clients in the pharmaceutical and health-related sectors. He then moved into the pharmaceutical industry full time, first at GSK and then at Pfizer. In each case he was in a statistical methodology group, not unlike the one he is currently in at Novartis. He has over eleven years' experience working in the pharmaceutical industry. He still maintains close connections with UK academia and holds Honorary/Visiting professorial positions at the London School of Hygiene and Tropical Medicine, University College London, University of Leicester and Queen Mary College, University of London. He is a Fellow of the American Statistical Association and the Royal Statistical Society and is the joint author of four statistical text books and over 100 peer-reviewed publications. He serves on several university advisory boards, including Oxford University, and is the chairman of the advisory board to the London Taught Course Centre. He is a Founding Editor-in-Chief of the journal *Pharmaceutical Statistics* and an Editor of the Biostatistics book series published by Chapman and Hall/CRC Press.

LECTURERS

Dr. Willi Maurer finished his studies of mathematics at the Swiss Federal Institute of Technology (SFIT) in Zürich with a thesis in decision theory in 1972. After postdoctoral studies, research and teaching activities at the Departments of Statistics at Yale University, Iowa State University and the University of Florida he joined the Medical Research Department of Sandoz as a clinical statistician in 1978 where he worked on projects in the CNS and immunology area before becoming head of Biostatistics Europe in 1983. In 2000 he was appointed head of the newly founded statistical methodology group in Novartis. From 1976 to 2002 Dr. Maurer lectured applied statistics at the Department of Pharmacy and other Departments of SFIT. He is especially interested in the development novel statistical methodology, related to multiplicity and adaptive designs that takes into consideration the interdisciplinary, ethical, economical and regulatory challenges to be faced in the design, analysis and interpretation of clinical trials. Since his retirement end of 2006 he serves as a statistical consultant to the Statistical Methodology group of Novartis' Development Department.

Dr. Heinz Schmidli studied Mathematics and Physics at the University of Basel, Switzerland, and received his PhD in Statistics in 1994. He started his work in industry as a statistician at CIBA-GEIGY, cooperating with scientists in research, pre-clinical and clinical development. In 2000 he joined the Modeling&Simulation department at Novartis, implementing model-based drug development in various therapeutic areas. Since 2007 he is a member of the Statistical Methodology department at Novartis, providing consulting to statisticians within the company, and enabling innovative statistical methodology. His main fields of interest are statistical modeling, Bayesian methods, and adaptive designs.
Heinz Schmidli is author or co-author of more than 30 publications in peer-reviewed journals, and author of a book.

Dr. Joerg Staeheli is a retired Novartis manager who was head of the internal consultancy unit Technology Planning & Transfer at the pre-merger company Sandoz. In his post-merger assignment he was in charge of Corporate Knowledge Networking and concurrently, the Secretary of the Novartis Technology Advisory Board and the Novartis Liaison Officer for the Industrial Liaison Program with the Massachusetts Institute of Technology (MIT). Joerg Staeheli then became departmental Head External Affairs, comprising tasks of alliance management, technology planning, and technology screening and assessment. Since his retirement, he has assumed mandates as business consultant in the biotech domain. Dr. Staeheli's background is in chemistry and management sciences. He is also an alumnus of INSEAD AMP.

LECTURERS

Ieuan Jones (BSC(tech),Cstat) is a statistician in the Research Statistics group at Novartis, in shaping the overall project strategy, development plans and risk mitigation for a variety of therapeutic areas. He has over 20 years' experience in the pharmaceutical industry of drug development from Pre-clinical to Phase III. Previous to Novartis he worked at Pfizer Sandwich (UK), where he also represented Pfizer's statistical position and negotiating with regulators. He is particularity interested in areas where statistics can add real value, through smarter study designs and decision criteria. He has successfully employed innovative statistical designs, such as Bayesian adaptive designs and other designs which have significantly reduced the cost of clinical trials and enabled earlier informed decisions. Ieuan has been responsible for the management and statistical leadership of various project teams and has represented projects at external expert panels, investigator meetings and internal technical management review boards. Prior to Pfizer, he worked as a statistician in the preclinical department at ICI pharmaceuticals (now Astra Zeneca). He has worked in diverse range of therapeutic areas. He graduated from the University of Wales, Institute of Science and Technology with a first class honors.

Wolfgang Schuette has received his MD from the University of Berlin. Further, he obtained commercial education in an MBA program at Henley Management College, UK. Throughout his 20 years in the pharmaceutical industry he worked in large as well as mid-cap and Biotech organizations - in clinical development, medical affairs, regulatory affairs, and marketing functions: as medical manager for Warner-Lambert in Germany, as product manager for Pfizer in Germany, and as medical director Middle Europe for Norgine, a mid-cap company. Prior to joining Novartis as Scientific Officer for Respiratory indications in November 2008 he served as Chief Medical Officer of Sirenade Pharmaceuticals (CNS and oncology) and Kenta Biotech (infectious disease and respiratory) where he each established and led the clinical development and regulatory affairs organization. During his career he has contributed to the successful development and marketing of several products in CNS, infectious disease, respiratory and gastroenterology indications, and worked with small molecules as well as biologics.

VENUE

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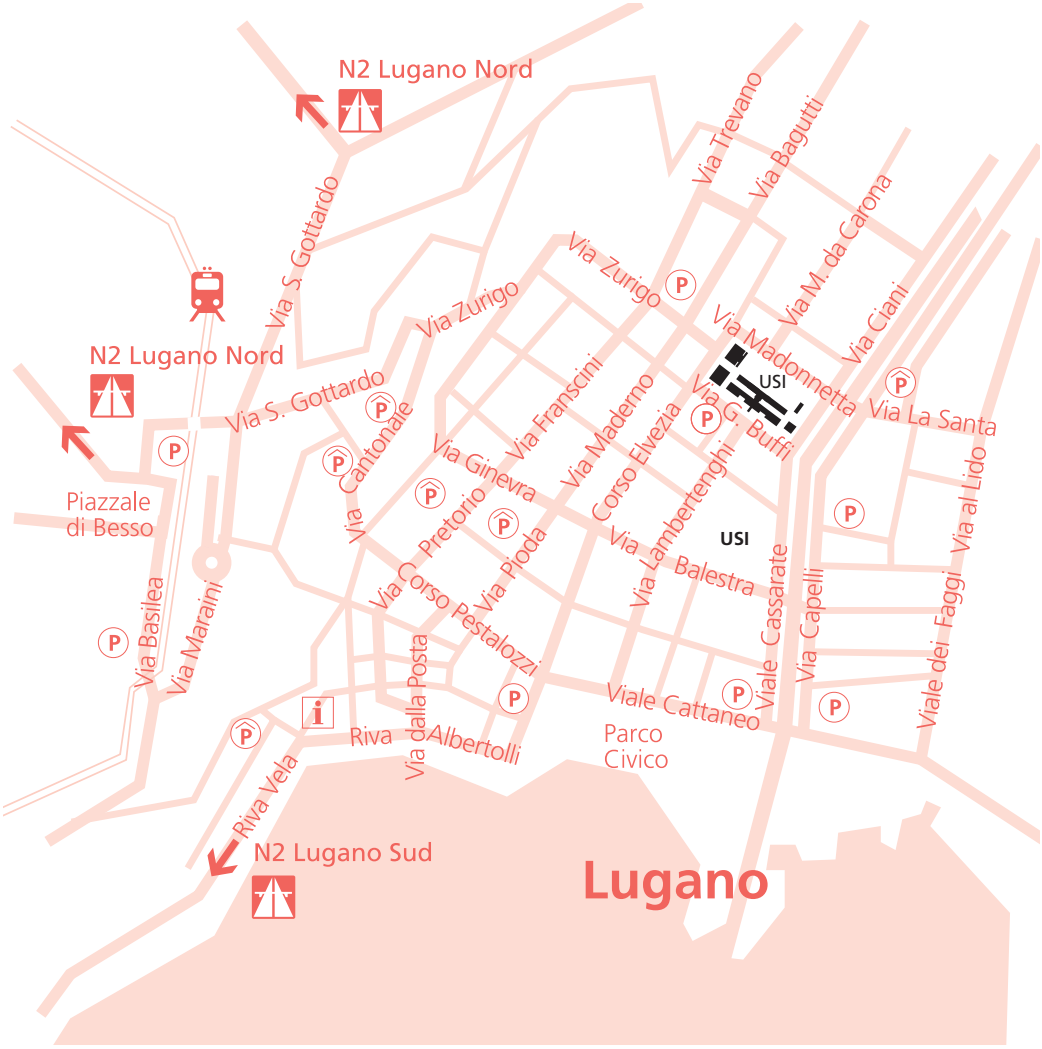

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FEES AND CONTACT DETAILS

CHF 400.-- (Early Stage Ventures/Academic Institutions)
CHF 600.-- (Medium-Sized Enterprises)
Deadline for registration: 15 June 2012
The number of participants is limited to 30.
Registration fees include tuition and hospitality (lunch, tea and coffee breaks).
The amount is payable in advance on receipt of confirmation of registration.

CONTACT

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