

Seminar 4/4 in the 2009 series on
clinical trials

Is the grass always greener over there?

**Pros and cons related to
conducting clinical trials in
selected world regions**

24/11/2009



SMERUD
Medical Research



Welcome to the House of Clinical Trials

- the one-stop shop for drug development



Clinical research 'theatre of dreams'

All in one place

- Smerud Medical Research CRO group
 - Contract Research: full-service phase I-IV
 - Clinical research training; incl. Medical statistics
- Forskningsklinikken AS
 - Patient recruitment (outpatients)
 - Bone disease screening (DEXA)
 - Outsourcing of study nurses
- Scandinavian Biotech Ventures AS
 - Venture capital – specialised on biotech
- SantoSolve AS
 - Biotech



Agenda 1/3

08:30 Welcome & introduction
Thor Amlie, Norwegian Bioindustry Association

Pre-seminar workshop on public (financial) incentives for clinical trials

08:35 Hvordan kan virkemiddelapparatet støtte preklinisk og klinisk utprøving av nye legemidler
Wilhelm R. Wold, spesialrådgiver, Innovasjon Norge, Oslo

Clinical trials in different geographical regions

09:00 The Nordic Area – 'baseline' characteristics
Knut Smerud, CEO, Smerud Medical Research International AS, Oslo

09:45 Clinical trials in Hungary
Melinda Varfi, Life Science expert at the Hungarian Investment and Trade Promotion Agency, Budapest

10:15 Coffee break



Agenda 2/3

- 10:30 Clinical trials in Czech Republic
*Knut Smerud, CEO, Smerud Medical Research International AS, Oslo
presenting slides on behalf of Daniela Vesela, Innovation Norway, Prague*
- 10:45 Clinical trials in the UK & Ireland
*Bob Macnair,
Director International Clinical Project Management,
Smerud UK, Edinburgh office*
- 11:30 Clinical trials in Russia
Tatiana Fedorova, Country manager, Smerud Russia
- 12:15 Lunch break
Light lunch provided on site.



Agenda 3/3

- 13:00 Clinical trials in the US
*Steven J Knox, Director Clinical Research,
Smerud Medical Research International AS, Oslo*
- 14:00 Coffee break
- 14:15 Clinical trials in the Far East: Japan, Korea, China, Taiwan, Thailand
Elisabeth Hagen, Regulatory Advice Management AS, Oslo
- 14:45 Round-table debate:
'How can Norway remain a competitive clinical trial market compared to other regions – for biotech companies or for big pharma?'
- 15:30 End of meeting



The Nordic Area - 'baseline' characteristics

Knut Smerud, CEO

*Smerud Medical Research International AS
Oslo*



Abbreviated CV speaker

Knut T Smerud

- Demographics & education:

- Norwegian, born 1963
- M.Sc. Degree, Oslo, 1989
 - Heterologous gene expression in yeast
- Business Candidate, Oslo, 2004
 - BI
- PhD student, Oslo/Uppsala, 2006-
 - Medical faculty
 - Bone disease in RTx

- Career

- Medical director,
 - Eli Lilly Norway, 1988-91
 - Bayer Norway, 1991-93
- Founder, CEO, chairman
 - Smerud Medical Research International AS (CRO), 1993-
 - Smerud Denmark ApS, 1996-
 - Smerud Finland Oy/AB, 1997-
 - Smerud Sweden AB, 1997-
 - Smerud Poland Sp.zoo., 2005-
 - Smerud UK Ltd, 2005-
 - Smerud Russia, 2007-
 - Smerud US Inc, 2009-
 - Forskningsklinikken AS, 2009-
 - Scandinavian Biotech Ventures AS, 2009-



Outline



- Demographics
- Regulatory affairs
- Number of CTAs/CTs
- Biotech/pharma companies
- USPs per country
- Pro & con analysis for region



Demographics and background

- Demographics:
 - Population: 25 million (estimate)
 - Common history and culture
 - Homogenous and low-mobile population of subjects and investigators
- Healthcare system similar across the region
 - Same tradition of medical care and treatment
 - Common procedures and processes
 - Command in English (verbally and in writing) quite good in all study team levels
- World leader in 'publications relating to clinical medicine' per capita
 - Top three countries (ISI, 2000):
 1. Sweden
 2. Denmark
 3. Finland
- Advanced telecommunication and IT
 - Complete medical history often computerized facilitating source data verification
 - World leaders per capita for mobile phones and internet access



Regulatory reputation (I)

- **Most preferred Member States**
(Number of rapporteur/co-rapporteurships 1995-2006)
 - ▶ Sweden 11%
 - ▶ UK 11%
 - ▶ Germany 10%
 - ▶ France 10%
 - ▶ Denmark 9%
 - ▶ Netherlands 9%
- **Reasons**
 - ▶ Reputation for efficiency of RMS
 - ▶ Reputation for scientific expertise of RMS
 - ▶ Applicants' previous experience with RMS
 - ▶ Lowest number of days for 'time-to-market'



Regulatory reputation (II)

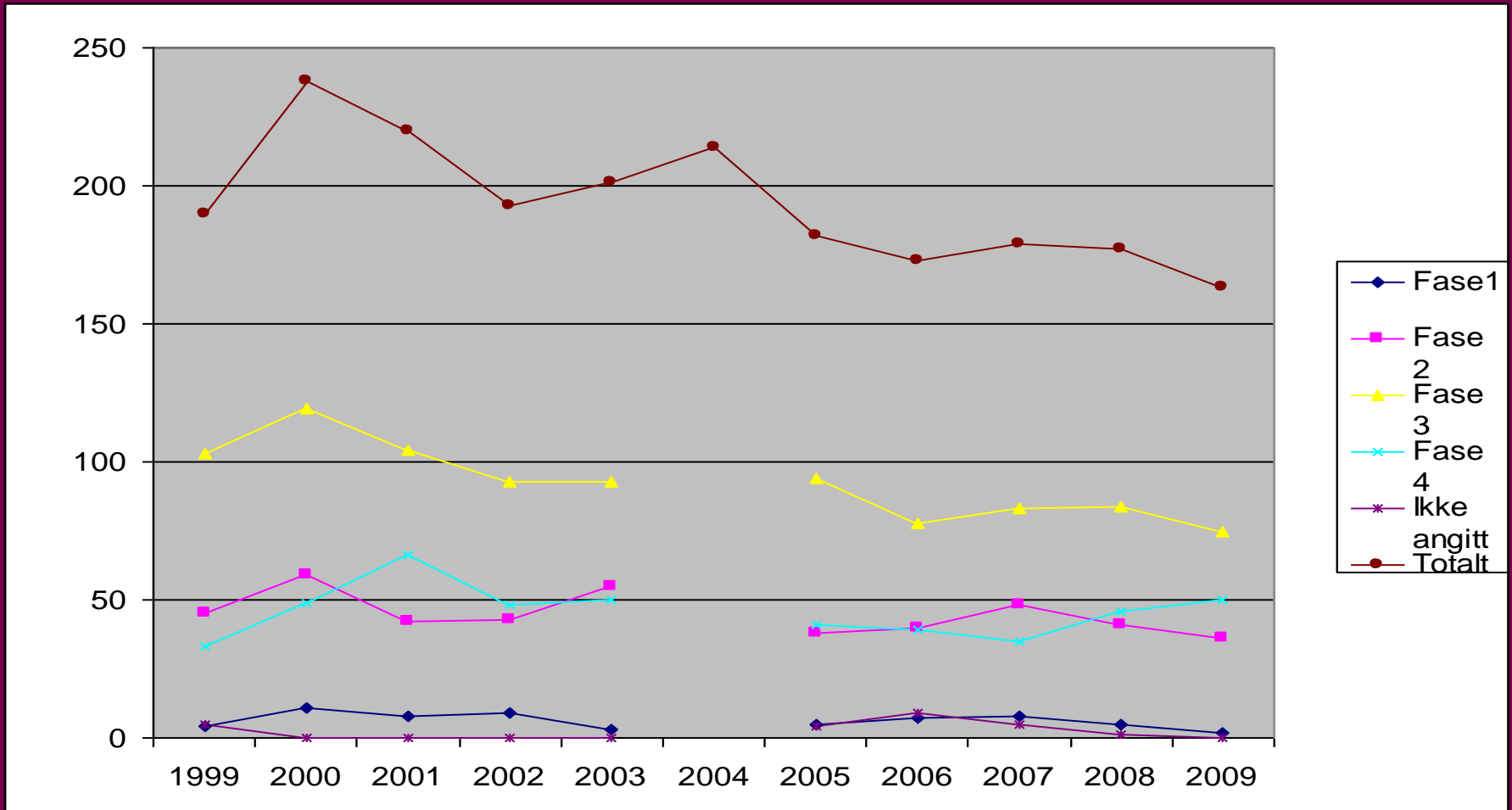
- clinical trial applications

- EU directive implemented
 - Compliance with set timelines (60 days)
 - The EC may request additional information only once before the final opinion is given
 - Only one national EC opinion is needed
 - The first ones to implement GCP guidelines (1989)



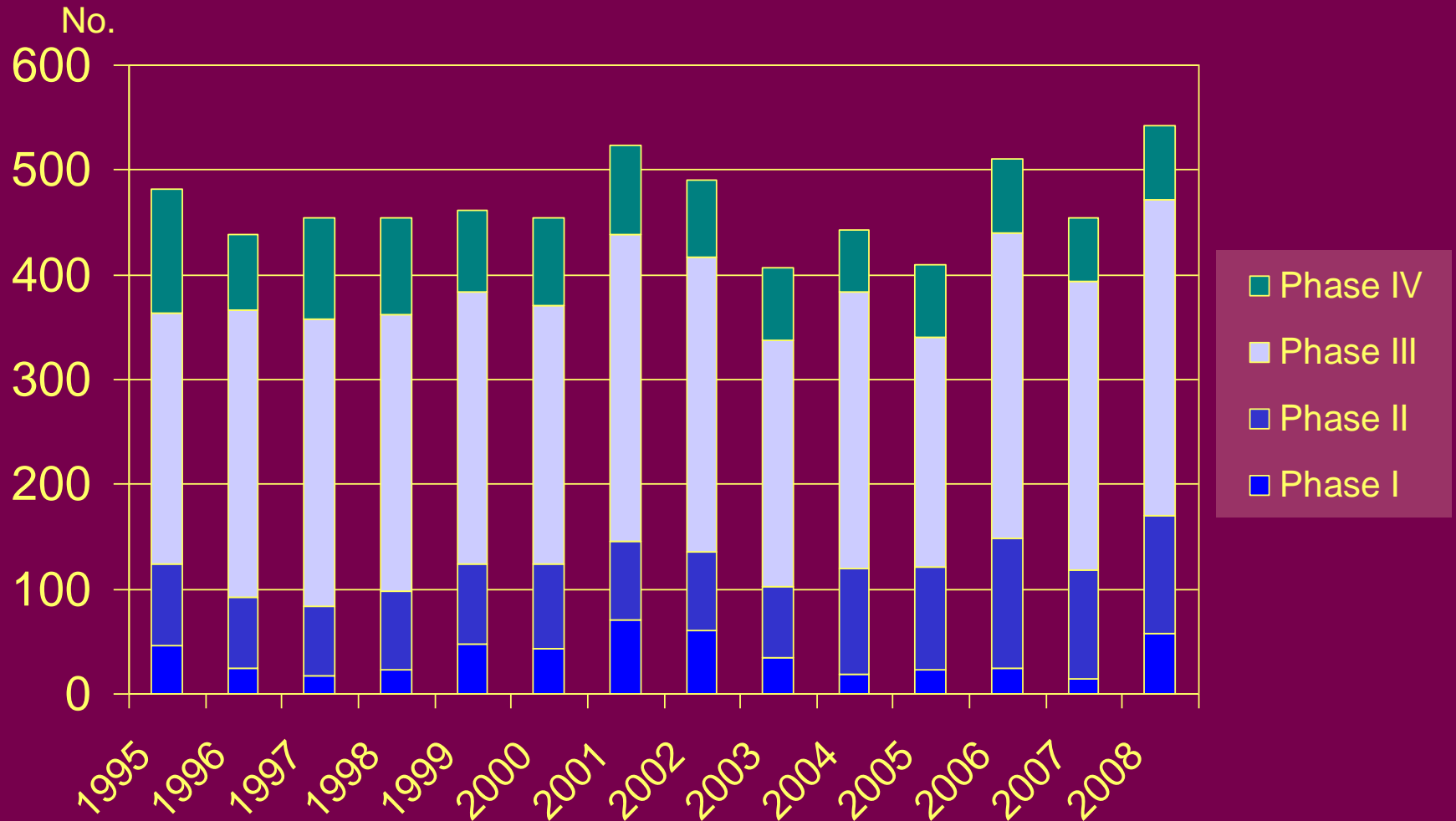
NORWAY: number of CTAs 1999-2009

(Source: Ingvild Aaløkken, SLV/NoMA, 09.11.2009)



Ongoing clinical trials in Finland

1995-2008



Company Product Pipeline by Country 2003

(Source: Mercer Sweden, ISI, 2004)

COUNTRY	Pre-Clinical	Phase 1	Phase 2	Phase 3	Total
UK	50	37	46	27	160
Switzerland	33	8	14	20	75
France	15	12	8	1	36
Germany	8	3	2	2	15
Ireland	2	2	2	5	11
Netherlands	4	1	1	0	6
Belgium	2	0	1	0	3
Sweden	13	7	8	1	29
Denmark	10	7	7	4	28
Norway	6	2	2	3	13
Finland	2	1	1	1	5
Nordic Area	31	17	18	9	75



Biotech&pharma companies

Norway

- Algeta
- Bionor Immuno
- Biotec Pharmacon
- Clavis Pharma
- Lytix biopharma
- Navamedic
- NutriPharma
- Nycomed Pharma
- PhotoCure
- Pronova
- Affitech
- AlgiPharma
- Avexxin
- A-viral
- BioMedisinsk Innovasjon
- Biosergen
- Lauras
- Orthogenics
- Regenics
- Reumatec
- SantoSolve
- siRNAsense
- Spermatech
- Thia Medica



Biotech&pharma companies

Denmark

- NovoNordisk
- Leo
- Lundbeck
- Ferring
- Affitech
- ALK-Abello
- Bavarian Nordic
- Bioporto
- Curalogic
- Genmab
- Lifecycle Pharma
- NeuroSearch
- Osteologics
- Pharmexa /Gemvax
- Rose Pharma
- Sanos Bioscience
- Topotarget
- Valderm
- Zealand Pharma
- Zymenex



Biotech&pharma companies Sweden

- AstraZeneca
- BioVitrum
- AcoHud
- Active Biotech
- Aerocrine
- AnaMar
- Bioinvent
- Cortendo
- Creative antibiotics
- Diamyd
- Karo Bio
- Medivir
- Oasmia
- Orexo
- Q-Med
- Q-Pharma
- SBL Vaccin
- Swedish Orphan Biovitrum
- Tripep



Biotech&pharma companies Finland

- Orion
- BioTie
- FIT biotech
- Hormos
- Ipsat Therapies
- Juvantia



Biotech&pharma companies Iceland

- deCode Genetics
- Iceland Genomics Corp.
- Remo
- Lyfjatrhou



Unique selling points per country

Norway

- Int'l opinion leadership in:
 - Cancer (incl registry)
 - Kidney Tx
 - Neuroscience
 - Rheumatology
- Health surveys
 - Research biobanks
 - Epidemiology
 - Population-based genomics



Unique selling points per country

Sweden

- MPA: 1st non-US agency acknowledged by FDA
- Karolinska Institute – world class medical training
- Established concept and training of research nurses
- Registers
 - Birth and Death
 - Hospital discharge
 - Cancer registry
 - Total population
- Int'l opinion leadership in:
 - Cardiology
 - Health economics and outcomes research



Unique selling points per country

Denmark

- Int'l opinion leadership in:
 - Cardiology
 - Diabetes
- CTA approval by day 30
- Strong pharma tradition



Unique selling points per country

Finland

- Int'l opinion leadership in:
 - Vaccination studies
 - Public health
- Infrastructure
- Education and training
- Work attitude



Nordic area - pros

- High success rate of attracting venture capital
- Investigator interest, commitment and reliability
- Excellent patient tracking systems enables efficient and reliable feasibility analyses
- Low mobility, ensures consistency among investigators for duration of studies
- High scientific credibility
- Committed patient populations
- High standard health care and financial coverage
- Good collaboration industry-academia-healthcare



Nordic area - pros

- Long-standing history of GCP
- Quick implementation of EU directives
- Efficient, transparent and foreseeable clinical trial application process
- Comprehensive national registries
- Data reliability
- Very low drop-out and lost-to-follow-up rates



Nordic area - cons

- Very small population even when combined
- Shortage of internationally experienced (biotech) business people
- Low mobility of international business experts
- Cost level in general
- Employment law
- Work attitude, esp for ages < 40
- Lack of public funding for SMEs, esp for clinical trials



Contact details
for further
information



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