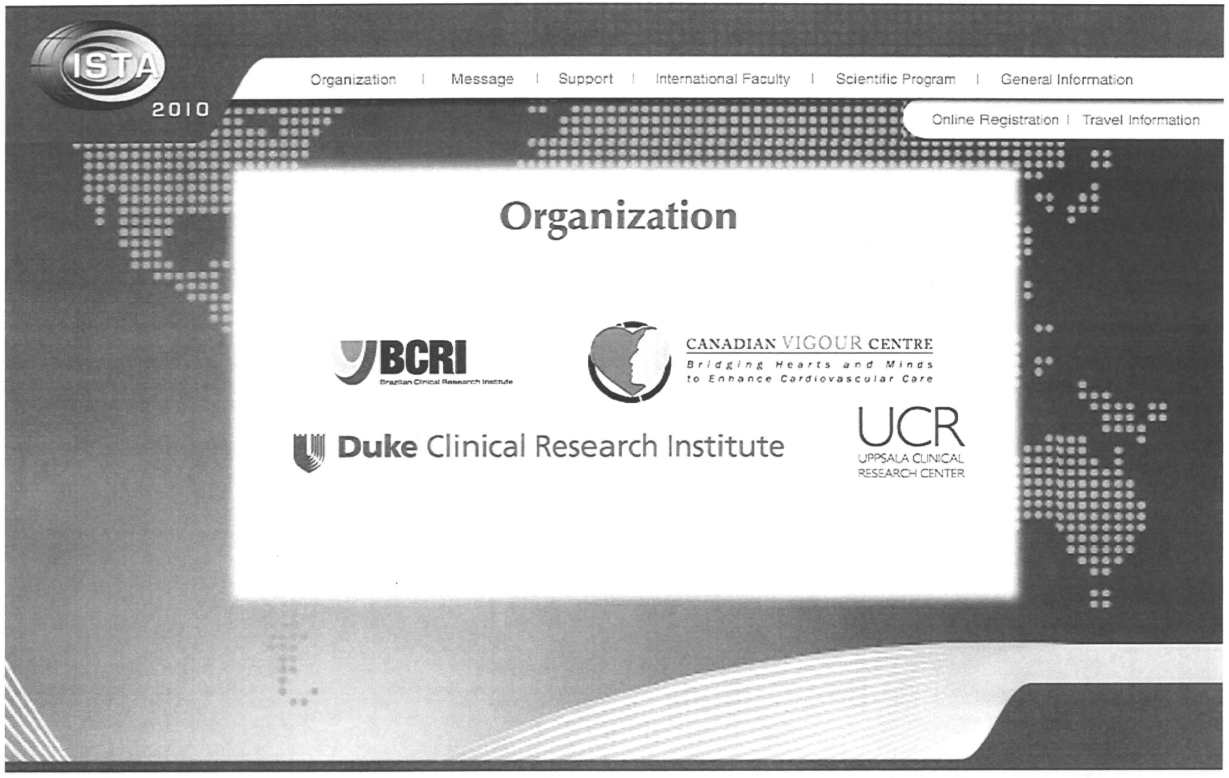
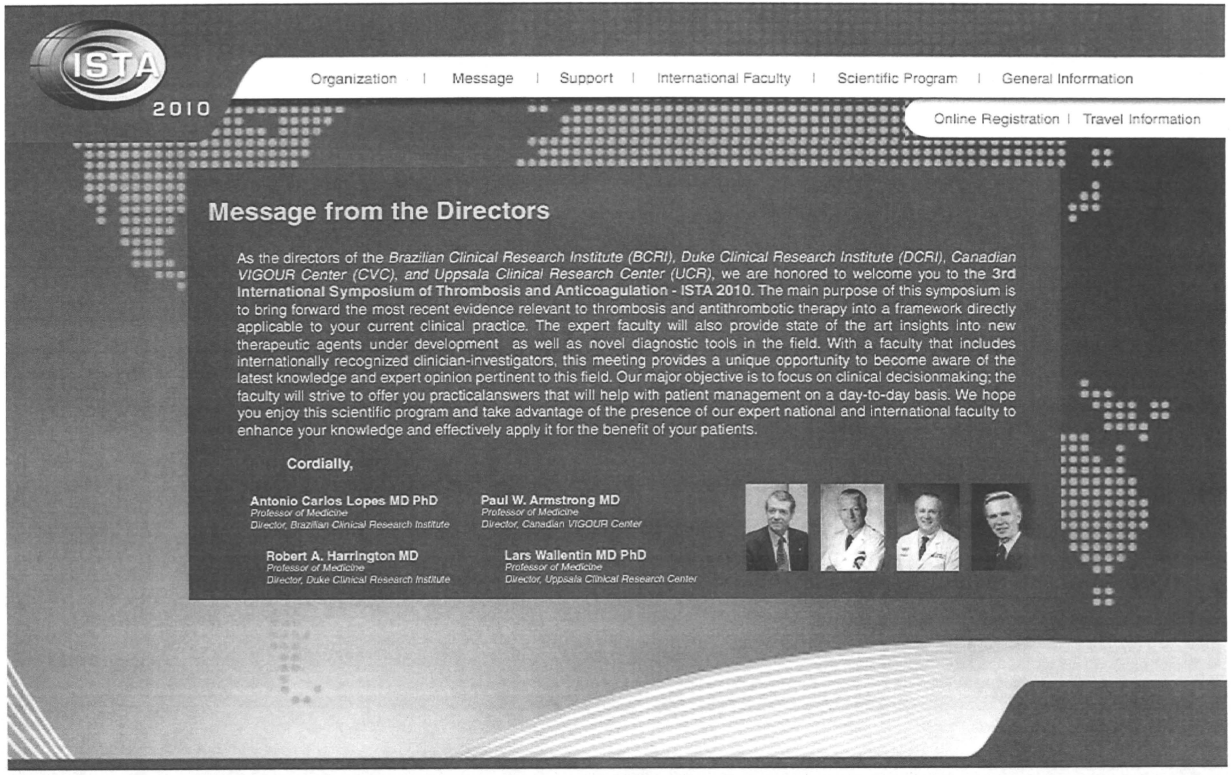
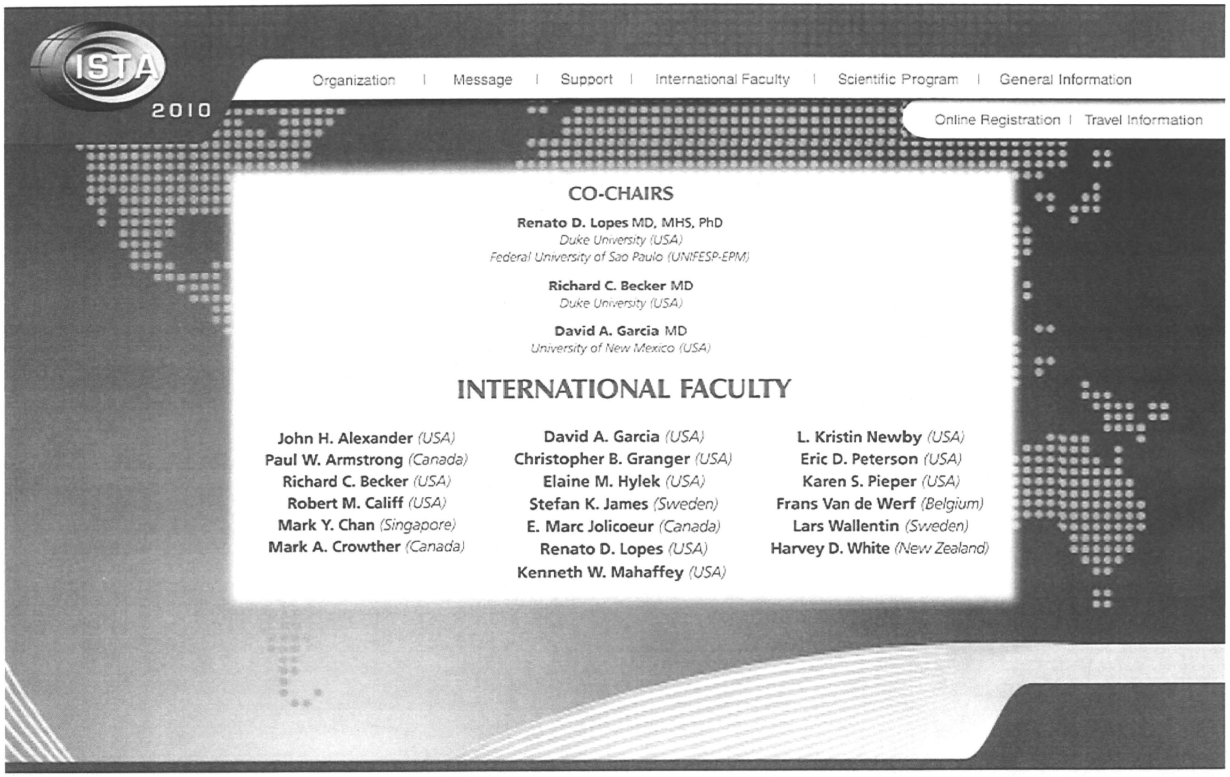

ISTA
2010
Organization | Message | Support | International Faculty | Scientific Program | General Information
Online Registration | Travel Information
Organization
BCRI
Brazilian Clinical Research Institute
CANADIAN VIGOUR CENTRE
Bridging Hearts and Minds to Enhance Cardiovascular Care
Duke Clinical Research Institute
UCR
UPPSALA CLINICAL RESEARCH CENTER


ISTA
2010
Organization | Message | Support | International Faculty | Scientific Program | General Information
Online Registration | Travel Information
Message from the Directors
As the directors of the Brazilian Clinical Research Institute (BCRI), Duke Clinical Research Institute (DCRI), Canadian VIGOUR Center (CVC), and Uppsala Clinical Research Center (UCR), we are honored to welcome you to the 3rd International Symposium of Thrombosis and Anticoagulation - ISTA 2010. The main purpose of this symposium is to bring forward the most recent evidence relevant to thrombosis and antithrombotic therapy into a framework directly applicable to your current clinical practice. The expert faculty will also provide state of the art insights into new therapeutic agents under development as well as novel diagnostic tools in the field. With a faculty that includes internationally recognized clinician-investigators, this meeting provides a unique opportunity to become aware of the latest knowledge and expert opinion pertinent to this field. Our major objective is to focus on clinical decisionmaking; the faculty will strive to offer you practicalanswers that will help with patient management on a day-to-day basis. We hope you enjoy this scientific program and take advantage of the presence of our expert national and international faculty to enhance your knowledge and effectively apply it for the benefit of your patients.
Cordially,
Antonio Carlos Lopes MD PhD
Professor of Medicine
Director, Brazilian Clinical Research Institute
Paul W. Armstrong MD
Professor of Medicine
Director, Canadian VIGOUR Center
Robert A. Harrington MD
Professor of Medicine
Director, Duke Clinical Research Institute
Lars Wallentin MD PhD
Professor of Medicine
Director, Uppsala Clinical Research Center


ISTA
2010
Organization | Message | Support | International Faculty | Scientific Program | General Information
Online Registration | Travel Information
CO-CHAIRS
Renato D. Lopes MD, MHS, PhD
Duke University (USA)
Federal University of Sao Paulo (UNIFESP-EPM)
Richard C. Becker MD
Duke University (USA)
David A. Garcia MD
University of New Mexico (USA)
INTERNATIONAL FACULTY
John H. Alexander (USA)
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Robert M. Califf (USA)
Mark Y. Chan (Singapore)
Mark A. Crowther (Canada)
David A. Garcia (USA)
Christopher B. Granger (USA)
Elaine M. Hylek (USA)
Stefan K. James (Sweden)
E. Marc Jolicoeur (Canada)
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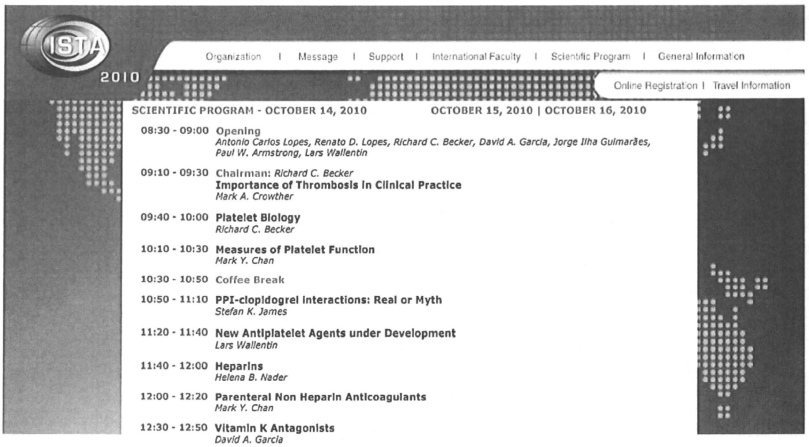
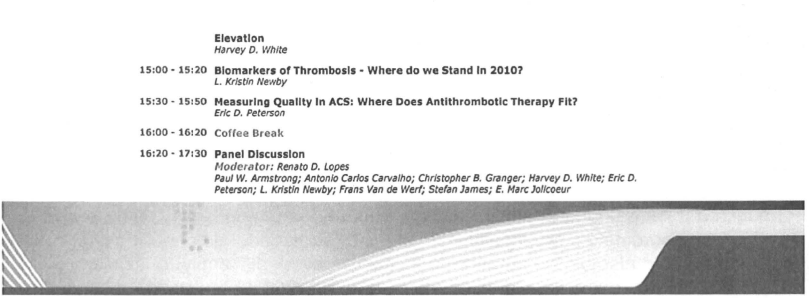
Frans Van de Werf (Belgium)
Lars Wallentin (Sweden)
Harvey D. White (New Zealand)


ISTA
2010
Organization | Message | Support | International Faculty | Scientific Program | General Information
Online Registration | Travel Information
SCIENTIFIC PROGRAM - OCTOBER 14, 2010
OCTOBER 15, 2010 | OCTOBER 16, 2010
08:30 - 09:00 Opening
Antonio Carlos Lopes, Renato D. Lopes, Richard C. Becker, David A. Garcia, Jorge Ilha Guimarães, Paul W. Armstrong, Lars Wallentin
09:10 - 09:30 Chairman: Richard C. Becker
Importance of Thrombosis in Clinical Practice
Mark A. Crowther
09:40 - 10:00 Platelet Biology
Richard C. Becker
10:10 - 10:30 Measures of Platelet Function
Mark Y. Chan
10:30 - 10:50 Coffee Break
10:50 - 11:10 PPI-clopidogrel interactions: Real or Myth
Stefan K. James
11:20 - 11:40 New Antiplatelet Agents under Development
Lars Wallentin
11:40 - 12:00 Heparins
Helena B. Nader
12:00 - 12:20 Parenteral Non Heparin Anticoagulants
Mark Y. Chan
12:30 - 12:50 Vitamin K Antagonists
David A. Garcia
12:50 - 14:00 Break
14:00 - 14:30 Chairman: Paul W. Armstrong
Acute Coronary Syndromes with ST-Segment Elevation - Guidelines Perspective on Antithrombotic Therapy
Frans Van de Werf
14:30 - 15:00 Antithrombotic Therapy in Acute Coronary Syndromes with non-ST-segment


Elevation
Harvey D. White
15:00 - 15:20 Biomarkers of Thrombosis - Where do we Stand in 2010?
L. Kristin Newby
15:30 - 15:50 Measuring Quality in ACS: Where Does Antithrombotic Therapy Fit?
Eric D. Peterson
16:00 - 16:20 Coffee Break
16:20 - 17:30 Panel Discussion
Moderator: Renato D. Lopes
Paul W. Armstrong; Antonio Carlos Carvalho; Christopher B. Granger; Harvey D. White; Eric D. Peterson; L. Kristin Newby; Frans Van de Werf; Stefan James; E. Marc Jolicoeur

Virtual Coordinating Center for Global Collaborative Cardiovascular Research
Duke Clinical Research Institute

VIGOUR National Coordinating Center Meeting
Concept Sheet and Agenda
January 19 – 21, 2011
Duke Clinical Research Institute
Durham, NC, USA

Goals

The specific goal is to enhance capabilities of and collaboration among national coordinating centers for conducting international CV trials, with focus on developing countries and on emerging academic leaders. The broader goal is to improve global cardiovascular clinical research capability.

Unmet needs

Many clinical investigators around the world are involved in some aspect of coordinating clinical trials. From the perspective of global clinical trial coordination, however, both standardized approaches and sufficient capabilities are lacking at national coordinating centers. Currently global commercial contract research organizations (CROs) take most of the responsibility for operational functions that might better be accomplished by local expert clinical investigative collaborators. From the perspective of the national coordinating centers, there is a lack of support to guide the development of capabilities, secure a pipeline of clinical research and trial activities, and establish sustainable "business models" to establish successful academic coordinating centers for clinical research and trials. In most countries there is a need for authoritative, knowledgeable, like-minded, patient focused, continuing, and reliable national expertise. There is also a major need to identify, develop, and nurture the next generation of global leaders in clinical research and trials.

What defines success?

From the perspective of national coordinating centers, success would be an increase in the number of clinically relevant and meaningful clinical trials and enhanced coordinating responsibilities, funding, and academic opportunities. Success would also be the creation of a social network or "family" of similarly motivated and directed individuals dedicated to the VIGOUR mission1 of enhancing world cardiovascular health by creating, implementing, and evaluating novel strategies developed through global collaboration.

From the perspective of global coordination (VIGOUR, DCRI, other AROs, NIH, industry sponsors), success would include improved metrics of trial operations, including time to regulatory approval, first patient enrolled, number of investigators, rates of enrollment, patient retention, data completeness and timeliness. Success would include a greater capacity to create and perform relevant trials most likely to improve care within the constraints of contemporary

economic realities and differing health care resources and systems among VIGOUR partners.

Another important goal is to enhance collaborative spirit and social interchange.

Goals of the meeting

Overall goal: Improve CV health by promoting global academic-based collaboration in an organization of clinical research focused on treatments for cardiovascular disease.

Specific course goals: **Provide understanding of the mechanisms to**

- Improve the capacity for collaborative meaningful clinical trials
- Better adjust the clinical trial methodology to current economic realities
- Integrate clinical trials into the health care systems by registry based trials
- Enhance coordinating opportunities, responsibilities and funding
- Improve all aspects on operations in ARO-coordinated clinical trials
- Increase academic clinical research opportunities in clinical trials
- Learn from differing health care systems among collaborating partners
- Contribute to a social network of academic collaborating investigators and sites

Meeting parameters

- Attendees: clinical/academic leader and, when available, an operational leader, from 15 to 20 mostly "emerging" national coordinating centers
- Organized by VIGOUR (including DCRI, Canadian VIGOUR Centre, Uppsala Clinical Research Center)
- Format: 3 days, with emphasis on discussion, problem solving, and workshops

Dates: January 19-21, 2011

Location: R David Thomas Center and DCRI, Durham, NC

- Funding: coverage of room, board, and all meeting expenses in Durham; travel expenses to be covered by national coordinating centers, with $1000 funding allowance per coordinating center to partially cover cost.

Output to include:

- Membership in the VIGOUR interactive communication network for improved collaboration in global clinical research and trials
- Access right to shared protected electronic networking space for the VIGOUR based clinical research and trials
- Personal link to specific senior VIGOUR mentors for continuing relationship/advice
- Investigator training slide set modules
- Patient retention modules
- Principles for steering committees, data sharing, etc
- A broad goal for output is a living document to serve as a "national coordinating center manual of operations." The plan would be have an advanced outline of this document by the end of the meeting.

Preliminary Agenda

Day 1: Detailed Center by Center Review

7:00 to 8:00 Breakfast

8:00-8:15 Welcome and Introductions

8:15 – 9:45 Goals and anticipated output

- What are commercial sponsors looking for in AROs/national coordinating centers?
- What is DCRI looking for in national coordinating centers, Why AROs?
- What are national coordinating centers looking for in sponsors and global AROs?

9:45-10:00 Break

10:00- 12:00 Detailed Center by Center Review

Center by center SWOT review of current status
Operational structure of national coordinating centers
Business models
Each coordinating center will have key parameters displayed on a poster, and present 5 slides with the current structure, business model, and SWOT analysis

Plan for 15 min presentation, 15 minute discussion per center
Group centers by region: Asia, South America, Eastern Europe, North America

Featured coordinating center presentation

12:00 – 1:00 Lunch (assigned seating)

1:00 – 1:30 Discussion

1:30 – 3:00 Detailed Center by Center Review (continued)

3:00 – 3:15 Break

3:15 – 5:00 Detailed Center by Center Review (continued)
5:00- 5:15 Current state of global CV trials

5:15 – 5:30 Wrap-up and Plans for Day 2

6:30 Reception followed by dinner (off site)

Dinner presentation: Industry vision for future of global clinical research

Day 2
7:00 – 8:00 Breakfast

8:00 – 8:20 NHLBI initiatives in Global Health
8.20 – 8.30 Discussion

8:30 – 9.30 Optimizing Investigator Networks
Investigator network models
DCRI Global Clinical Research Education and Training program
Communications: newsletters, meetings, etc
Discussion

9.30 – 9.45 **Developing your academic team: mentoring, fellow training, opportunities for international training**
9.45 – 10.00 Discussion

10:00 --10:15 Break

10:15 – 10.35 Integrating Trials, Electronic Health Records, and Registries

10.35 – 10.45 Discussion

10.45 – 11:00 Information technology to support networks
11.00 – 11.20 – Vision of Information technology to support Clinical Research
11.20- 11.35 Discussion

11.35 - 12.15 Regulatory Expertise
11.35 – 11.55 FDA Perspective
11.55 – 12.10 Discussion
12.10 – 12.20 How to build relationships with national regulatory authorities; what regulatory expertise do you need and how do you get it?
12.20 – 12.35 Discussion

12.35 – 1.30 Lunch

Trial Quality

1.30– 1.45 How can we define and use quality metrics, guiding principles, to improve performance? (IRB submission, approval, contracting, patient enrollment, patient retention, etc)

1.45 – 2.00 Discussion

Breakouts 2.00 – 2.50, 2.50 – 3.40

How can we track and improve enrolment, data quality, protocol and study drug adherence, follow-up?

Refining a common set of investigator training materials
How to build a small ARO

Manuscripts, analyses, database capabilities

3.50 – 5.00 How to be successful financially

3.50 – 4.10 Business models for national coordinating centers
4.10 – 4.25 Discussion
4.25 – 4.40 Contracting and securing a research pipeline; collaborative opportunities
4.40 – 5.00 Discussion

5.00 – 5.15 Day 2 Wrap Up
Plans and game rules for Day 3

5:30 – Optional Tour of DCRI

6.15 Group dinner

Day 3
7.00 – 8.30 Breakfast

Proposal competition and role playing

Three teams to develop and present proposals for robust National Coordinating Center role in a hypothetical global CV trial: how do you position and promote yourself to be successful?

Base on a brief RFP to be provided before the meeting

8:30 to 10:30 **Groups meet and develop proposals**

10:30 – 10:50 **Break**

10:50 to 12:00 **Group presentations and discussion**

12.00 – 12.30 Meeting Closing
12.30 Evaluation and feedback, and box lunches

Questions to address:

Research priorities

- What should the focus for meaningful clinical research and trial opportunities be for the next decade?
- What are the important traditional clinical trial principles and where are the new opportunities?
- How may we integrate clinical trials and research into registries and the health care system electronic patient records?

Operational improvement

- How can we improve operational structure of national coordinating centers; job descriptions of key employees, component activities (site development, training and management; business development and management; events adjudication; analysis and publication)?
- How can national coordinating centers take the responsibility for and perform site management in monitoring?
- How can we develop and/or improve clinical trial and registry investigator networks, training, and management?
- How can we better implement business models, business development, and financial management for clinical research and trials?
- How can we better negotiate and sign contracts with Pharma and funding agencies?
- How can we improve negotiation and contract agreements among academic clinical trial centers?
- How can we perform and improve data management, including site databases and ability to track site performance metrics?
- How can we better manage regulatory responsibilities, including establishing and fostering relationships with national regulatory authorities?
- How can we move towards rational simplification, streamlining, efficiency of trial processes?

- How can we organize and run core laboratories in different areas?
- How can we be more efficient in organizing and performing clinical events adjudication?
- How can we appropriately balance needs of ethics/IRBs/informed consent issues?

Academic mission, substudies, communication, education

- How can we improve communications among national coordinating centers, academic and operational colleagues?
- How can we improve ability to perform clinical trial statistics, primary and secondary analyses, publications?
- How can you promote and participate in other clinical research opportunities in a global collaboration including with NHLBI and similar funding agencies?
- How can you achieve academic credit and advancement by participation in collaborative clinical research and trials?
- How can we organize collaborative and effective presentation and publication based on appropriate authorship guidelines?
- How can we better promote and organize clinical research by substudies?
- How can we better organize and collaborate in blood and tissue sampling and biobanking?
- How can we use public relations/ communication in a global and local environment?

1. http://vigour.dcri.duke.edu/

CLINICAL RESEARCH CENTER CHIBA UNIVERSITY HOSPITAL NATIONAL UNIVERSITY CORPORATION, JAPAN

Hideki HANAOKA MD., PHD.
Yasuhisa FUJII MS.
Masaya KOSHIZAKA MD., PhD

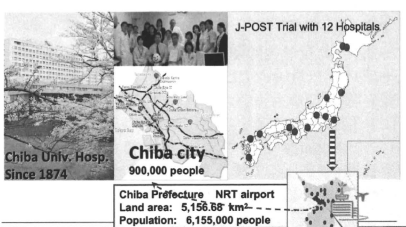
Background and History of Chiba Univ. Hospital Clinical Research Center

- Chiba Univ. Hosp. ARO funded by MHLW 2007~
  - Chiba Prefecture Clinical study network Center funded by PMDA 2004~2006
  - Site Based Research Center of Chiba Univ. Hospital 2000~ (>100 NDA protocol / 2010)
- OUR MISSION: To ensure the ethical and scientific integrity of clinical research
- Construct close relationship with other AROs and become partner of multinational clinical trials

Snapshot of Coordinating Center

- Year coordinating center established : 2006 with Chiba study (Atherosclerosis. 2008 201:345-52.)
- 34 staffs (ARO 13, Research Nurse 13, admin office 7)
- 12 University hospitals in Japan and 50 clinics in Chiba Prefecture in our network
- Ongoing (current) trials:
  - Japanese POEMS Syndrome with Thalidomide Trial (J-POST trail) placebo control DBRCT with 12 hospitals: IND Aug.16. 2009
  - Other trials using PRS and CDM: 23 trials
- Organized under Chiba University Hospital.

Location of coordinating center, and site distribution



Strengths

- Strong leadership of the president of University
- Constructing of flexible organization
- Excellent PI
- Excellent operation and project management team
- Personal relationship with PMDA reviewer

Weaknesses

- Education of clinical research professional
- Small number of staffs
- Relationship with pharmaceutical companies are not strong
- Small number of clinical trails coordinating by our self
- PIs and site MDs are too busy and have low incentive (motivation)

Opportunities

- Starting new IND trials and Asian trails
- Attending world wide clinical trail as Japanese leading ARO
- Developing site network
- Developing official relationship with national regulatory Agency

Threats

- Under weakening Japanese economic power
- Growing cost of clinical trails $1 = 82 yen

臨床試験を受ける患者の看護③

同意説明された後の患者の
関わりについて考えてみよう♪

日本看護協会　看護者の倫理綱領

4、看護者は、人々の知る権利及び自己決定の権利を尊重し、その権利を擁護する

事例紹介①

80才代　女性
診断名：両変形性膝関節症
平成15年11月頃より上記診断にて近医通院。
変形強く、疼痛も強い。アルツ（リウマチ性疾患補助薬）にて治療していたが、疼痛増強し、手術
（人工膝関節形成術）希望し、当院紹介となる。
既往歴：高血圧にて降圧剤（ノルバスク5mg・ディオバン80mg）内服心拡大指摘され心エコーするが、
心機能は問題ないといわれる。

事例紹介②

今年X月　当院受診
医師からは、手術もできないことはないが、
年齢的なことや術後のことなど考え、手術ではなく、JNS024ERの治験をすすめた。
治験の話に興味を持ち、よく説明は聞いていた。
その日は、同意説明文書を渡し、よく考え次回、
返答をいただくことにした。

説明内容
～医師から～

・手術希望ということだが、年齢や高血圧、心臓のことなど考えるとオピオイド鎮痛薬等で疼痛コントロールしてみることも一つの手段である。
・現在JNS024ERの治験が始まり、基準も満たすので、参加してはどうか？
・治験薬の期待される効果・有害事象・プラセボがあること、この試験に参加されない場合の治療方法など、簡単に説明される。

説明内容
～CRC～

・治験とは？
・再度プラセボが必要な理由
・具体的な試験の進め方、スケジュールについて
・試験的要素を含むこと。そのため、期待される効果が必ずしも出るとは限らない。また、未知の有害事象が出現する可能性がある
・その他18項目に沿って事務手続きやプライバシーの保護について説明した。

場面

後日、患者さんから
『治験の場合は、痛みはよくなるのですか？』
『プラセボというのはなんですか？』
『家族は、手術した方がいいと言っている』
『手術と治験どちらがいいかわからない』
『せっかく先生にすすめていただいたけど、根本的な治療をしてほしい』
などと訴えがありました。

このような場合、どのように関わりますか？

ポイント

- 本人・家族は、痛みが良くなってほしいが、疼痛の原因を治したいと考えている
- せっかく先生が言ってくれたのにという思いがある
- 治験はプラセボがある

まとめ

治験参加の有無を決定する場面において、患者の気持ちに寄り添って考えられるのは、やはり看護師だと思われる。
臨床試験に参加しようか迷っている患者、これから参加しようと考えていても不安を持っている患者、これらの患者に安心して、臨床試験や、通常診療が受けらるよう支援することが必要だと考えられる。

まとめ②

そのためには、患者が何を不安に感じ、何を希望しているのか確認し、自己決定するにあたり、患者の思い、必要な情報など整理する。
臨床試験、通常診療それぞれのメリット・デメリットを考えながら、その場で、患者と決めるのではなく、患者の気持ちを医師やCRCへ伝え、情報交換していくことが必要だと考えられる。

選択36　　臨床試験を受ける患者の看護　　第1回

実施日：平成22年9月17日（金）
参加数：23名
回答数：19名

1 今日のセミナーは有意義でしたか

はい	18
いいえ	0
どちらともいえない	0
回答なし	1
総計	19

2 講義の時間は適切でしたか

長い	3
適切	15
短い	0
回答なし	1
総計	19

3 治験・臨床試験の違いについて理解できましたか

はい	16
まずます	1
どちらともいえない	1
回答なし	1
総計	19

4 臨床試験を行う上での倫理について理解できましたか

はい	13
まずます	1
いいえ	0
どちらともいえない	2
回答なし	3
総計	19

5 治験コーディネーターの業務についてイメージできましたか

はい	15
いいえ	0
どちらともいえない	2
回答なし	2
総計	19

6 当院での臨床試験の現状が理解できましたか

はい	15
まずます	1
いいえ	0
どちらともいえない	1
回答なし	2
総計	19

7 臨床試験を受ける患者に対する臨床看護師の役割について理解できましたか

はい	16
いいえ	0
どちらともいえない	0
回答なし	3
総計	19

8 本日のセミナーに参加し、今後の業務に役立ちますか

はい	11
いいえ	0
どちらともいえない	5
回答なし	3
総計	19

9 治験などについて日頃疑問に思っていることなどはありますか

はい	2
どちらともいえない	0
いいえ	11
回答なし	6
総計	19

9 具体的に

- 自主臨床試験はいつも医師がいつの間にやら行っていて、看護師は何がなんだかよく分からずにいる状態です。看護師にも情報が来るようにするには一体どうすればよいのかと思っています。
- バイタル測定の回数が普段より多かったり、土日に薬剤を作成をするのが、負担になることがある

10 今後、どのような内容のセミナーを希望されますか

- 治験がどんな風に行われたとか、どんな介入をしたとか、例があればイメージがわくのかも

11 その他、ご意見ご感想があればお書きください

- 治験・臨床試験はあくまで「研究」であって、それを被験者が「治療」だと説得するのは、倫理的に問題を生むと思いますが、現場ではこの問題にどのように対応されているのでしょうか？
- よくわかりました

選択36　　臨床試験を受ける患者の看護　　第2回

実施日：平成22年10月22日
参加数：22名
回答数：16名

1 今日のセミナーは有意義でしたか

はい	16
いいえ	0
どちらともいえない	0
回答なし	0
総計	16

2 講義およびグループワークの時間は適切でしたか

長い	4
適切	10
短い	1
回答なし	1
総計	16

3 臨床試験の必要性について理解できましたか

はい	16
いいえ	0
どちらともいえない	0
回答なし	0
総計	16

4 臨床試験の実施計画書（プロトコール）ついて理解できましたか

はい	13
いいえ	0
どちらともいえない	3
回答なし	0
総計	16

5 臨床試験の概要を理解するコツがわかりましたか

はい	15
いいえ	0
どちらともいえない	1
回答なし	0
総計	16

6 当院での臨床試験のシステムについて理解できましたか

はい	14
いいえ	0
どちらともいえない	2
回答なし	0
総計	16

7 臨床試験を受ける患者に対するあなたの役割について理解できましたか

はい	13
いいえ	0
どちらともいえない	3
回答なし	0
総計	16

8 本日のセミナーに参加し、今後の業務に役立ちますか

はい	15
いいえ	0
どちらともいえない	1
回答なし	0
総計	16

9 その他、ご意見ご感想があればお書きください

- わかりやすく説明してくれたのでありがとうございました。
- 患者に対する説明文がかなり分かりやすいので、今後は役に立てたい。

10 今後、どのような内容のセミナーを希望されますか

- 治験の研修がもっと多くてもいい。知らないことが多いので、重要性を多くの人が理解できるためにも治験後の結果なども研修などで知らせてもよい。入院後どうなったか、病棟Nsは知りづらい。
- CRCの具体的な活動
- いろいろな事例が知りたいと思います。