

犬が吠えてもFERCAPという名の私たちの列車は進む（進行を阻むような力が働いても、FERCAPの活動は続いてゆく）。

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これからのFERCAP

Kenji Hirayama, M.D., Ph.D.

アジア西太平洋地区倫理委員会フォーラム (Forum for Ethical Review Committees in the Asian and Western Pacific Region [FERCAP]) の10年間の実り多い経験を経た今、運営委員会の新旧メンバーにとっての唯一の懸案事項は新しい委員長である。というも、彼は今のところ日本から参加している唯一のFERCAPのアクティブメンバーであるからだ。しかし、これが私たちの唯一の懸案事項であることから、私は非常に楽観的な見方をしている。

私たちの誰もが気付いている通り、交通手段や通信機器の発達により、世界はだんだん小さくなっている。実際に、フェイスブックのようなインターネットコミュニティは、いくつかの国では政府を変えるような民主主義運動を引き起こしている。私は、建設的な変化の方法をもたらすことにおいてそのような現代科学技術を高く評価しているが、同時に、バーチャルなものはバーチャルでしかなく、真のコミュニケーションを行うには顔と顔をつき合わせた接触が間違いなくもっと必要とされているということも確信している。もちろん、今から10年たてば、もっと素晴らしい技術が登場してそのようなバーチャルな状況を塗り替えるだろう。

緊密なコミュニケーションに関しては、FERCAPは地区内において理想的なコミュニティの形成を促進してきている。私たちの活動に参加する倫理委員会 (ECs) / 治験審査委員会 (IRBs) が増えており、それらの委員会の審査の質は非常に劇的に進歩している。そのような成果に基づいて、私は委員長として次の3つの主要議題、すなわち、EC/IRBの審査手法の品質の継続的な向上、国の認定システム構築への支援強化、公衆衛生のための倫理的な製品研究開発の推進への取り組みを進めたいと考えている。

EC/IRBの審査手法の品質の継続的な向上

私たちは今、地区内のECs/IRBsの品質管理の第2相に移行しようとしている。この第2相では、私たちの調査および評価のシステムを維持するために多数の第2世代のFERCAP調査担当者が必要である。FERCAPの教育・訓練プログラムは、あらゆる利用可能な技術および手段を利用してさらに強化されるだろう。

国の認定システム構築への支援強化

EC/IRBの審査手法の品質の継続的な向上に関連して、各国の社会が信頼し得るように品質を改善するために各国が自国の認定システムを設けることを私たちは強く提案している。自国の認定システムを設立しようとする取り組みを私たちは支援するつもりである。

公衆衛生のための倫理的な製品研究開発の推進

私たちはこの10年間、自分たちの社会やコミュニティに役立つような最終成果を夢見て共に努力してきた。この夢を実現するためにはEC/IRBの品質は必要不可欠であり、同時に地区における公衆衛生ニーズを満たすための製品の研究開発活動を推進するために、地区内でさらなる人的資源を必要とするだろう。これに関連して、6つの大学、すなわち、長崎大学、東京大学、タマサート大学 (Thammasat University)、チュラロンコン大学 (Chulalongkorn University)、上海第二軍医大学 (Shanghai Second Military Medical University)、アンティオキア大学 (Universidad de Antioquia) (コロンビア) は、保健ニーズに応える *医薬品研究開発ディプロマコース (Diploma Course on Product Research and Development to Meet Public Health Needs)* を通じて6年前に提携を結んでいる。第5回目のコースは2011年10月10日から11月1日にかけて長崎で開催された。このコースは最終的に各大学の博士課程につながることとなる。FERCAPは、これらのディプロマおよび博士プログラムに対して、倫理に関する部分の提供を引き続き手助けするつもりである。

期待された以上の成果

私は相乗効果という言葉が好きである。相乗効果は私たちの情熱から生まれるだろう。私は、FERCAPが提案された議題に沿った進歩だけでなく、期待された以上の進歩を遂げることを期待している。

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Atoy M. Navarro (Philippines)
Research Fellow

COMPLIMENTS FROM FERCAP PARTNERS

COMPLIMENTS FROM DCUMC IRB

The Daegu Catholic University Medical Center Institutional Review Board (Since 1998)

The institutional official who has authority over the *Daegu Catholic University Medical Center Institutional Review Board* (DCUMC IRB) is **Ho Gak Kim M.D., Ph.D.** Within DCUMC IRB are two IRBs: IRB for drug and all biomedical research that has **Oh Dae Kwon M.D., Ph.D.** as chairman with two panels and IRB for medical device that has **Ho Gak Kim M.D., Ph.D.** as chairman with one panel.

The DCUMC IRBs are responsible for protecting the rights and welfare of human subjects in research projects conducted by the faculty and staff of the institution. The DCUMC IRBs review all human subject research projects done by the faculty and staff of Daegu Catholic University Medical Center. The DCUMC IRBs try to comply with the agreements underlying human safety assurances by satisfying institutional policy as well as national policy [*Korean Good Clinical Practice* (KGCP)] and international policies and regulations including the *Declaration of Helsinki*.

The DCUMC IRBs were registered at the *United States (U.S.) Office for Human Research Protections (OHRP)/Federalwide Assurance (FWA)* in 2006 which was followed by the recognition from the *Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)/Forum for Ethical Review Committees in the Asian and Western Pacific Region (FERCAP)* in November 2008. The DCUMC IRBs are scheduled to receive re-recognition in November 2011. Two members of the DCUMC IRBs (**Im Hee Shin Ph.D.** and **Sang Gyung Kim M.D., Ph.D.**) have been devoted in promoting quality ethical review in the region by working as SIDCER/FERCAP surveyors. The DCUMC IRBs have good collaborations with SIDCER/FERCAP as well as with the *Korean Association of Institutional Review Boards (KAIRB)* and the *Western Institutional Review Board (WIRB)*.

This November 20-23, 2011, DCUMC IRBs have the exciting challenge of hosting the *11th FERCAP Annual International Conference and FERCAP General Assembly* in Daegu, South Korea.

COMPLIMENTS FROM DCUMC IRB

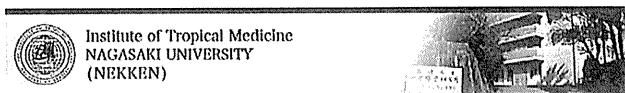
Panel 1 (Drug & Biomedical Research)	Panel 2 (Drug & Biomedical Research)	Panel 3 (Medical Device)
Oh Dae Kwon M.D., Ph.D. <i>Chairman</i>	Oh Dae Kwon M.D., Ph.D. <i>Chairman</i>	Ho Gak Kim M.D., Ph.D. <i>Chairman</i>
Im Hee Shin Ph.D. <i>Expert Secretary</i>	Jung Kyu Kim M.D., Ph.D. <i>Secretary-General</i>	Im Hee Shin Ph.D. <i>Expert Secretary</i>
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Tea Young Choi M.D. <i>Member</i>	Mi Jung Eun <i>Member</i>	Jin Tae Jung M.D., Ph.D. <i>Member</i>
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Jong Seok Park Ph.D. <i>Member</i>	Seung Deok Gang <i>Member</i>	Jong In Youn Ph.D. <i>Member</i>
Kyu Suk Kim <i>Member</i>	Kyu Suk Kim <i>Member</i>	Hyun Dong Chae M.D. <i>Member</i>
Tae Sik Lim <i>Member</i>	Su Ho Lee <i>Member</i>	Sung Won Youn M.D., Ph.D. <i>Member</i>
		Ki Cheul Sohn M.D. <i>Member</i>
		Jong Seok Park Ph.D. <i>Member</i>
		Su Ho Lee <i>Member</i>
Myung Hyun Lee <i>Staff</i>	Myung Hyun Lee <i>Staff</i>	Hae Oak Yoo <i>Staff</i>
Hyun Jung Park <i>Staff</i>	Hyun Jung Park <i>Staff</i>	
	Chang Yeol Lee <i>Administrative Secretary</i>	



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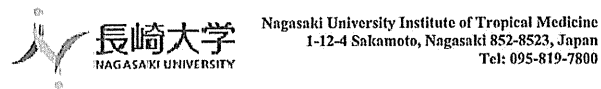
COMPLIMENTS FROM NEKKEN



The tropics, the most ecologically diverse region on Earth, present an ongoing complexity of tropical diseases and other health problems. In view of the remarkable advances made in the field of international exchange in recent years, it is imperative that these problems be addressed from a global perspective. Based on this understanding, the *Institute of Tropical Medicine, Nagasaki University* (NEKKEN), aims to overcome tropical diseases, particularly infectious diseases, and the various health problems associated with them, in cooperation with related institutions and organizations, to strive for excellence in the following:

- Spearheading research in tropical medicine and international health
- Making global contribution through disease control and health promotion in the tropics by applying the fruits of research
- Cultivating researchers and specialists in tropical medicine and international health

It is in view of these goals that NEKKEN supports the capacity building initiatives for ethical health research of the *Strategic Initiative for Developing Capacity in Ethical Review* (SIDCER)/*Forum for Ethical Review Committees in the Asian & Western Pacific Region* (FERCAP). The last 10 years saw NEKKEN and SIDCER/FERCAP working together in programs such as the *International Course on Research Ethics* and the *Diploma Course on Product Research and Development to Meet Public Health Needs* of Nagasaki University. Kenji Hirayama, M.D., Ph.D. of NEKKEN is currently FERCAP Chair. In the years to come, NEKKEN and SIDCER/FERCAP will continue to work for ethical research in tropical medicine and international health especially in the Asia-Pacific region.



COMPLIMENTS FROM WFCMS-ERC



The *World Federation of Chinese Medicine Societies* (WFCMS) is an international academic organization with its headquarters in Beijing, China. Currently there are 201 member institutions covering 58 areas/countries registered with this organization. WFCMS is devoted to promoting understanding and cooperation among academic groups of Chinese Medicine all over the world, strengthening international academic exchange, improving their qualifications for Chinese Medicine, protecting and developing Chinese medicine, working to have Chinese Medicine gain access to the mainstream of medical system in various countries, promoting exchange and cooperation among Chinese Medicine and other medicines in the world and, therefore, making greater contributions to the health of mankind.

Under the approval of the Ministry of Civil Affairs last September 2010, the *Ethics Review Committee of the World Federation of Chinese Medicine Societies* (WFCMS-ERC) was formally established during the *Inaugural and the First Annual Academic Conference of Ethics Review Committee of the World Federation of Chinese Medicine Societies* (WFCMS-ERC 2011) held in Nanjing, China on November 19-20 2011. WFCMS-ERC is constituted by volunteers worldwide who are interested in ethical review of Chinese Medicine clinical research. It mainly consists of personnel who work on Chinese Medicine clinical research, biomedical research, or Traditional Medicine clinical research, and ethical review of research. The goals of WFCMS-ERC are to standardize and improve the capacity of ethical review of Chinese Medicine clinical research through academic study, cooperation and communication, quality assessment and criteria developing; to study and discuss characteristics of clinical research of Traditional Medicine and its impact on ethical review; and finally, to contribute to promoting respect and protection of subjects' rights and safety. For more information, please refer to <http://www.wfcms.org/>.

COMPLIMENTS FROM THE DAEGU HOST AND SUPPORTERS

11th FERCAP International Conference
Innovation, Integration and Ethical Health Research
 Hotel Inter-Burgo, Daegu, South Korea
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VI. 研究成果の刊行に関する一覧表

研究成果の刊行に関する一覧表

書籍

著者氏名	論文タイトル名	書籍全体の編集者名	書籍名	出版社名	出版地	出版年	ページ
熊谷雄治	Chapter2-3 インペ アード・パフォーマンス	編集-宮地良樹、岡 本美孝、谷内一彦	ファーマナビゲ ーター抗ヒスタ ミン薬編	メディカ ルレビュー 社	東京	2012	56-60
熊谷雄治	第3章 バイオ/抗 体医薬品の臨床試 験の留意点、バイオ /抗体医薬品の開 発・製造プロセス- 開発・解析・毒性・ 臨床・申請・製造・ 特許・市場-		情報機構		東京	2012	59-68
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<p>Takenami T, Wang G, Nara Y, Fukushima S, Yagishita S, Hiruma H, Kawakami T, Okamoto H.</p>	<p>Intrathecally administered ropivacaine is less neurotoxic than procaine, bupivacaine, and levobupivacaine in a rat spinal model.</p>	<p>Can J Anaesth</p>	<p>59</p>	<p>456-465</p>	<p>2012</p>
<p>Ryuge S, Sato Y, Jiang SX, Wang G, Matsumoto T, Katono K, Inoue H, Iyoda A, Satoh Y, Yoshimura H, Masuda N.</p>	<p>Prognostic impact of nestin expression in resected large cell neuroendocrine carcinoma of the lung.</p>	<p>Lung Cancer</p>	<p>77</p>	<p>415-420</p>	<p>2012</p>
<p>熊谷雄治</p>	<p>第14回臨床薬理試験研究会セッションII「新薬開発における心毒性評価」、新薬開発における心毒性評価；現状の問題点と将来</p>	<p>臨床医薬</p>	<p>28(10)</p>	<p>931-956</p>	<p>2012</p>
<p>熊谷雄治</p>	<p>国内臨床試験における心臓安全性評価の現状と将来</p>	<p>谷本学校毒性質問箱</p>	<p>14</p>	<p>20-35</p>	<p>2012</p>
<p>熊谷雄治</p>	<p>臨床研究のススメ(13)国際共同試験, 我が国の課題</p>	<p>最新医学</p>	<p>67(5)</p>	<p>121-124</p>	<p>2012</p>
<p>熊谷雄治</p>	<p>臨床の立場から 今後の心臓リスク評価への期待等</p>	<p>谷本学校毒性質問箱</p>	<p>14</p>	<p>64-67</p>	<p>2012</p>
<p>熊谷雄治</p>	<p>第3回DIAカーディアック・セイフティ・ワークショップ 心臓安全性評価学の進展 "Assay sensitivityはまた全てのTQT試験に必要な" 賛成の立場から: Assay sensitivity is required and can take many forms</p>	<p>臨床医薬</p>	<p>29(1)</p>	<p>29-32</p>	<p>2013</p>
<p>Jun Tanaka, Hidefumi Kasai, Kenji Shimizu, Shigeki Shimasaki, Yuji Kumagai</p>	<p>Population pharmacokinetics of phenytoin after intravenous administration of fosphenytoin sodium in pediatric patients, adult patients, and healthy volunteers.</p>	<p>Eur J Clin Pharmacol</p>	<p>69(3)</p>	<p>489-97</p>	<p>2013</p>
<p>熊谷雄治</p>	<p>早期臨床試験の国際展開の中で日本の進むべき方向性：臨床評価</p>	<p>臨床評価</p>	<p>40(2)</p>	<p>288-295</p>	<p>2013</p>

VII. 資料

1. 国際共同治験への取り組み、第4回ライフイノベーション地域協議会
2. 初期臨床試験用量設定のための非臨床試験の考慮事項、개발자를 위한 비임상시험 국제 워크숍 (臨床研究・開発者のための非臨床試験国際ワークショップ)
3. スペシャルポピュレーションの信頼性確保、臨床薬理
4. 臨床研究のススメ (13) 国際共同治験, 我が国の課題
5. 週刊 医学のあゆみ 「First-in-Human 試験の実際」

国際共同治験への取り組み

-神奈川発の新薬を世界へ-

北里大学臨床試験事業本部
熊谷雄治



国際誌掲載論文から見た日本の医学研究

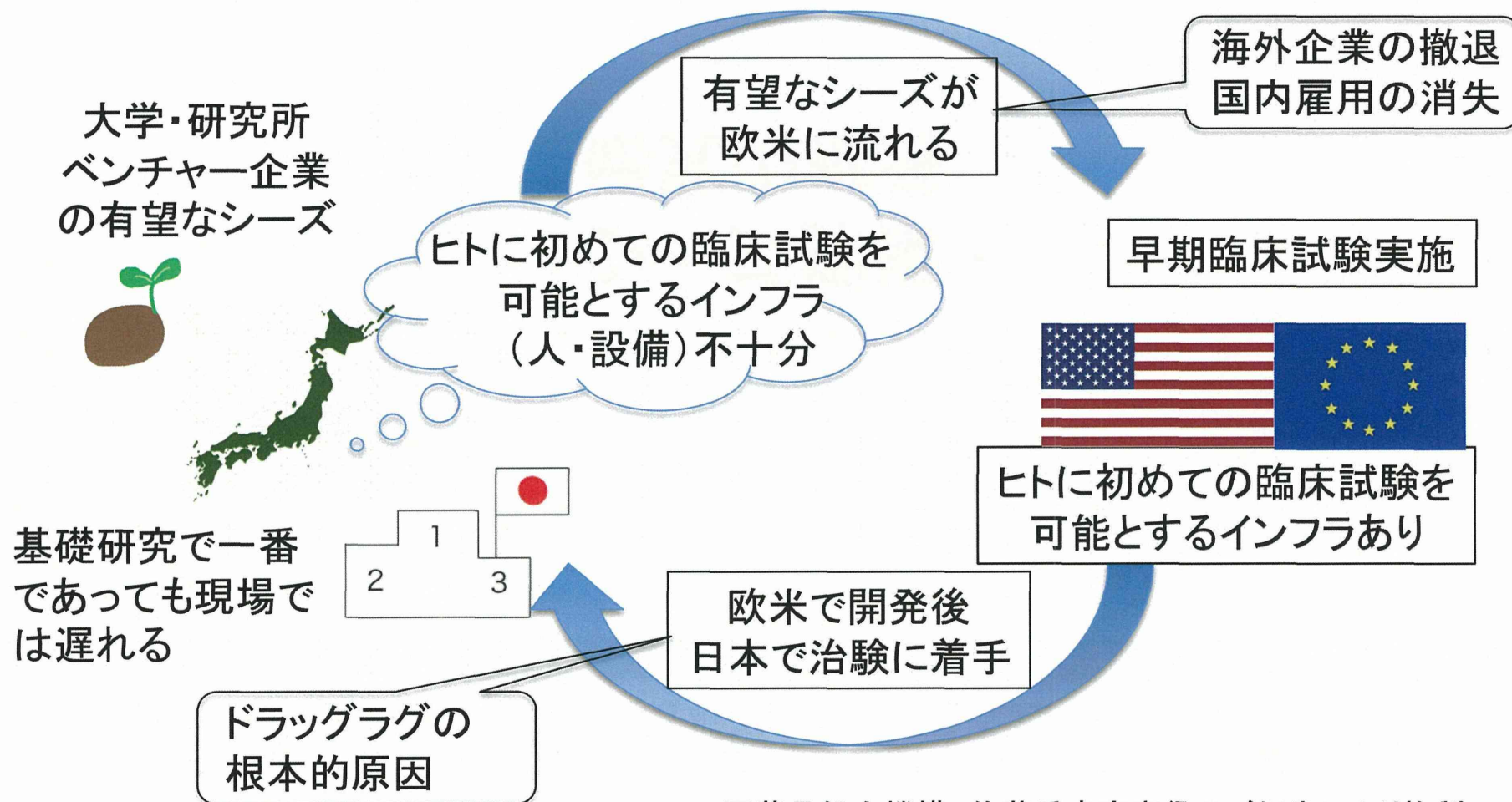
	寄与率	順位
基礎医学		
Cell	7.3%	4 th
Nature	6.7%	5 th
Science	6.6%	5 th
臨床医学		
NEJM	1.7%	12 th

*C-index*で見ると、国際的共同臨床試験の論文数は24位

臨床医学研究の現状と強化への取り組み～臨床発表データを用いた国際比較～
政策研ニュース 2008年10月

現状の医薬品・医療機器開発の問題点

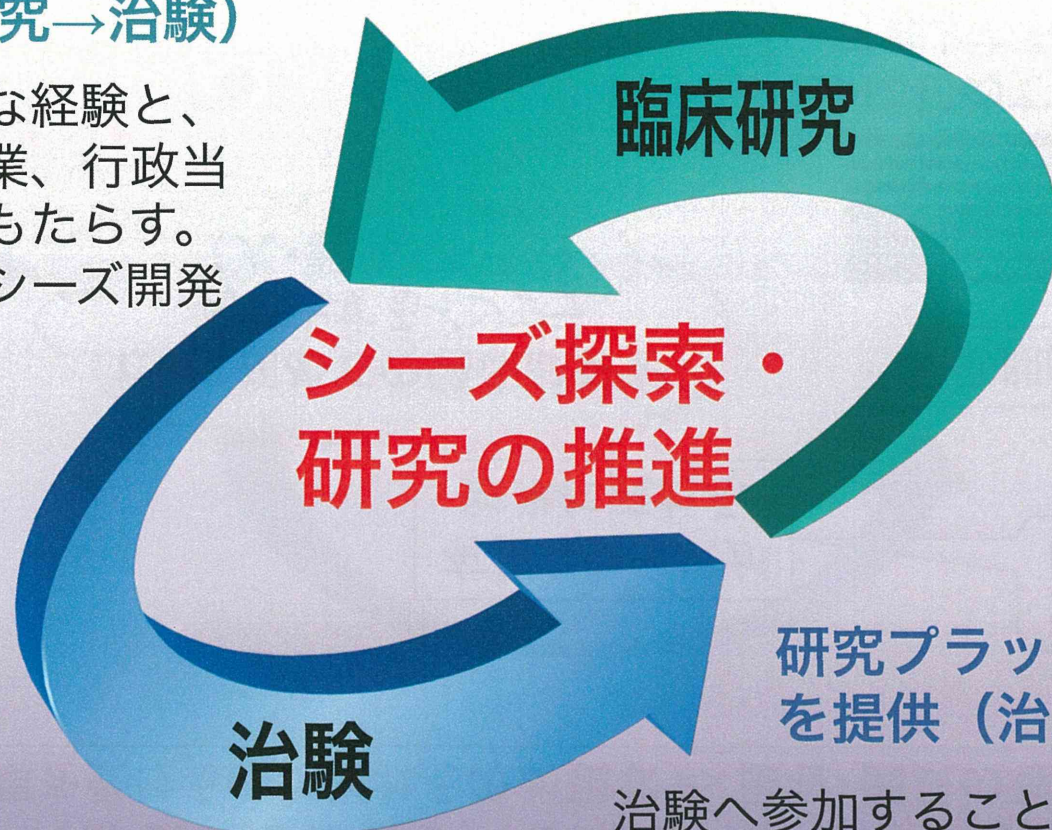
日本初のシーズであるにもかかわらず、欧米での臨床試験・開発が先行し、日本の患者がその恩恵を受けるのが遅れるのが現状 => 患者・国民の理解が得られない。



臨床研究と治験の相互補完関係

臨床開発プラットフォーム を提供（臨床研究→治験）

臨床研究の豊富な経験と、
 学術的背景は企業、行政当
 局の高い信頼をもたらす。
 アカデミア発のシーズ開発
 も可能となる。



研究プラットフォーム を提供（治験→臨床研究）

治験へ参加することにより、
 薬効評価の基本、品質管理の概念を
 学ぶことができる。治験のために整
 備された環境はそのまま臨床研究へ
 使用可能である。

臨床薬理研究所

- 研究試験獲得
- 知財手当
- 非臨床安全評価

データマネジメント部

海外戦略室

治験支援部

研究開発部

事業戦略部(窓口)

医学部
臨床研究センター

- プロトコール作成支援
- データセンター機能
- 人材育成・開発・研修
- 治験・臨床研究システム開発

ベンチャー企業

国内外医療機関

CRO・製薬企業

国内外研究者

シード探索

前臨床
コンサル

早期試験
実施

Ⅱ・Ⅲ相
試験支援

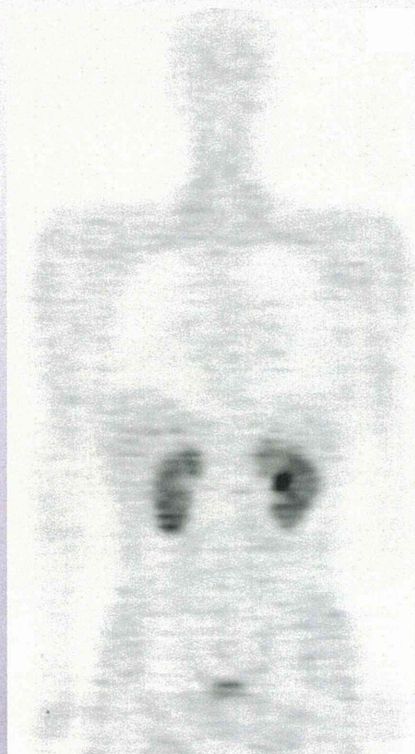
薬事申請
コンサル

臨床研究
・市販後調査
支援

診断・治療一体化戦略に基づく抗がん療法の実現（その1）

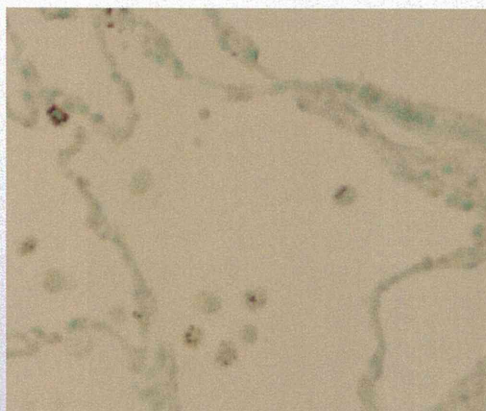
-がん特異的分子標的、LAT1によるがんの診断-

LAT1 PET

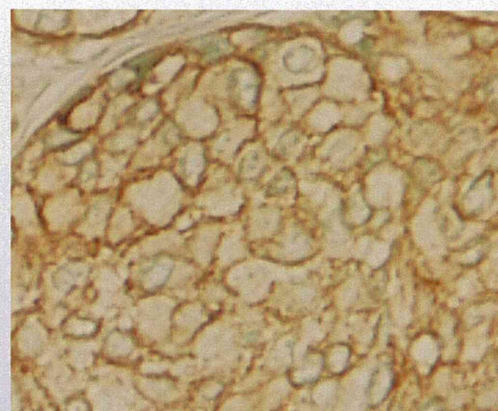


非がん

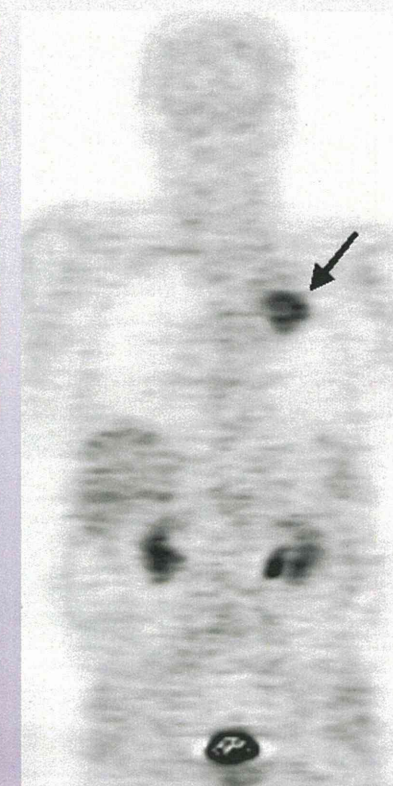
非がん肺組織



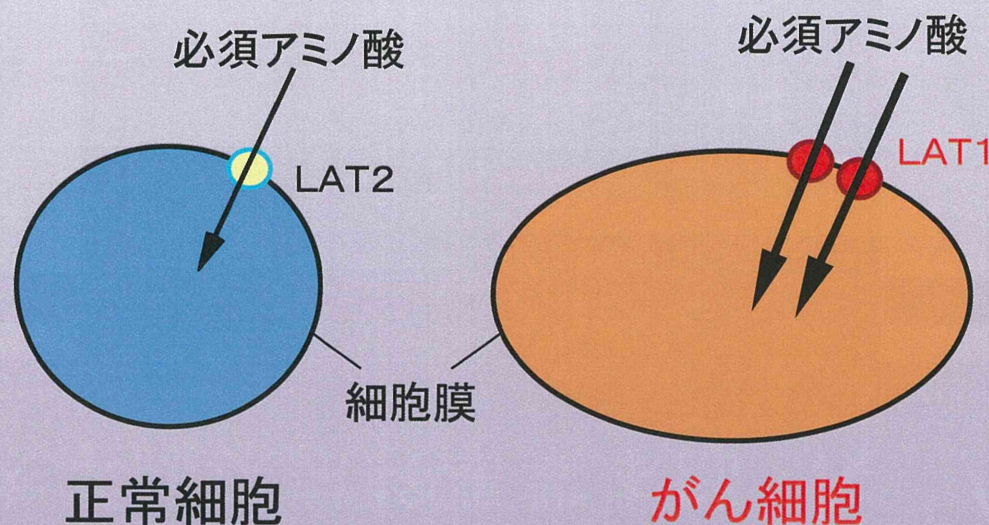
肺がん組織



LAT1 PET



肺がん



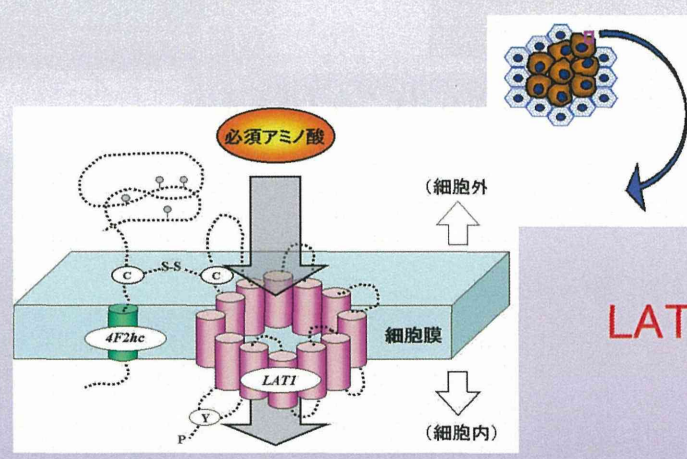
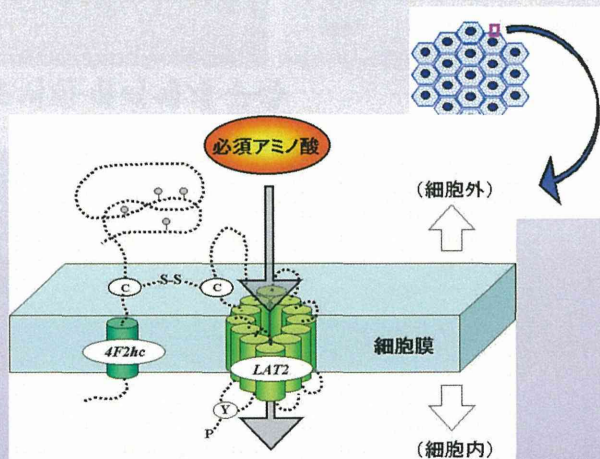
診断・治療一体化戦略に基づく抗がん療法の実現 (その2)

-LAT1の特異阻害薬、JPH203によるがんの治療-

(正常組織を構成する細胞膜の拡大模式図)

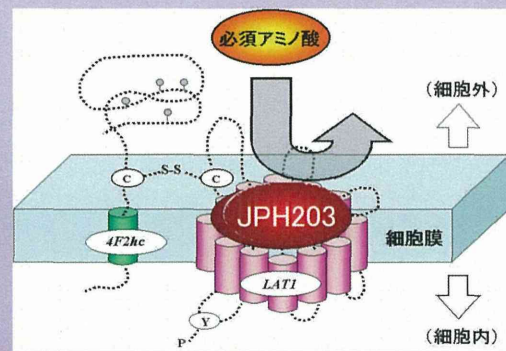
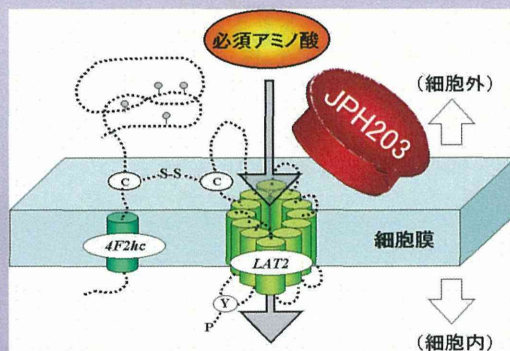
(がん組織を含むがん細胞膜の拡大模式図)

LAT2



LAT1

正常細胞膜



がん細胞膜

変化なし

細胞増殖停止、細胞死(アポトーシス)