第1回臨床研究専門委員会	資料　5
平成19年8月17日	藤原

平成19年8月18日

第1回臨床研究倫理指針に関する専門委員会　コメント

国立がんセンター中央病院
臨床検査部長・治験管理室長
藤原康弘

総合科学技術会議　基本政策推進専門調査会
「科学技術の振興及び成果の社会への還元に向けての制度改革について」

6．治験を含む臨床研究の総合的推進

（問題点）

○制度的枠組みの不備により臨床研究が遅れている

○新薬の承認審査体制の脆弱さ

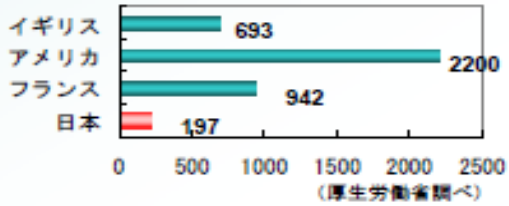
○新薬へのアクセスの遅れ（世界売上ﾄｯﾌﾟ医薬品の約3割が日本では未承認）

臨床研究での論文数の国別シェアの順位（2002）

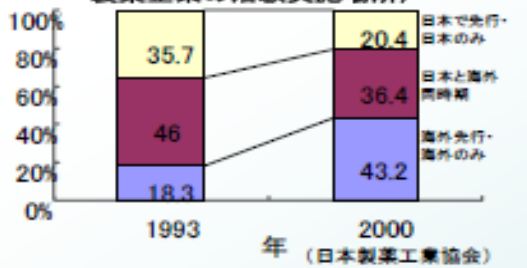
順位	臨床研究
1	アメリカ
2	イギリス
3	カナダ
14	日本

(N Engl J Med 2002;347(15):1211-12)

医薬品承認審査等の人員の国際比較（H17）



国内治験の空洞化（日本の製薬企業の治験実施場所）



（改革事項）

○「臨床研究に関する倫理指針」を改定し、臨床研究の準拠すべき実施基準を策定

○被験者の臨床研究への参加を促進するため、保険診療と研究に付随する診療が併用可能な保険制度を確立

○医薬品医療機器総合機構の審査体制の充実（機構の人員の拡大・育成等）

○国際共同治験の推進（ITを活用した施設間ネットワーク作りや治験に係る書類様式の統一化等）

等

平成18年12月18日

安心して臨床研究を実施するには

被験者保護　と

臨床研究振興　の

ふたつ（ブレーキとアクセル）の

整備が必要

米国 National Research Act ：
被験者保護を重視

PL 93-348, 1974 HR 7724
PL 93-348, JULY 12, 1974, 88 Stat 342
(Cite as: 88 Stat 342)

UNITED STATES PUBLIC LAWS
93rd Congress - Second Session
Convening January 21, 1974

DATA SUPPLIED BY THE U.S. DEPARTMENT OF JUSTICE. (SEE SCOPE)
Additions and Deletions are not identified in this document.

PL 93-348 (HR 7724)
JULY 12, 1974

1974年7月

An Act tO AMEND THE PUBLIC HEALTH SERVICE ACT TO ESTABLISH A PROGRAM OF NATIONAL RESEARCH SERVICE AWARDS TO ASSURE THE CONTINUED EXCELLENCE OF BIOMEDICAL AND BEHAVIORAL RESEARCH AND TO PROVIDE FOR THE PROTECTION OF HUMAN SUBJECTS INVOLVED IN BIOMEDICAL AND BEHAVIORAL RESEARCH AND FOR OTHER PURPOSES.

BE IT ENACTED BY THE SENATE AND HOUSE OR REPRESENTATIVES OF THE UNITED STATES OF AMERICA IN CONGRESS ASSEMBLED

この後、“コモン・ルール”と呼ばれる連邦規則ができ、詳細な臨床研究倫理規準が示されて、それにもとづいた研究がなされている

(1) THE SUCCESS AND CONTINUED VIABILITY OF THE FEDERAL BIOMEDICAL AND BEHAVIORAL RESEARCH EFFORT DEPENDS ON THE AVAILABILITY OF EXCELLENT SCIENTISTS AND A NETWORK OF INSTITUTIONS OF EXCELLENCE CAPABLE OF PRODUCING SUPERIOR RESEARCH PERSONNEL;

米国　Clinical Research Enhancement Act

公的研究費にもとづく臨床研究環境整備をうたった

Public Law 106–505
106th Congress

An Act

To amend the Public Health Service Act to provide for recon[illegible] Secretary of Health and Human Services regarding the plac[illegible] external defibrillators in Federal buildings in order to imp[illegible] of individuals who experience cardiac arrest in such buildings, and to establish protections from civil liability arising from the emergency use of the devices.

Nov. 13, 2000
[H.R. 2498]

2000年11月

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Public Health Improvement Act.
42 USC 201 note.

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Public Health Improvement Act".

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

NIHによる臨床研究助成の振興内容を細かく規定

http://www.fda.gov/cder/about/smallbiz/faq.htm#Types%20of%20INDs

Types of INDs

An Investigator IND is submitted by a physician who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. A physician might submit a research IND to propose studying an unapproved drug, or an approved product for a new indication or in a new patient population.

- Emergency Use IND allows the FDA to authorize use of an experimental drug in an emergency situation that does not allow time for submission of an IND in accordance with 21CFR , Sec. 312.23 or Sec. 312.34. It is also used for patients who do not meet the criteria of an existing study protocol, or if an approved study protocol does not exist.
- Treatment IND is submitted for experimental drugs showing promise in clinical testing for serious or immediately life-threatening conditions while the final clinical work is conducted and the FDA review takes place.

There are two IND categories:

- **Commercial.** These are applications that are submitted primarily by companies whose ultimate goal is to obtain marketing approval for a new product.
- **Research (non-commercial)**

Emergency and **Treatment INDs** are also known as "Compassionate" INDs, but the term "Compassionate" is not in the IND regulations.