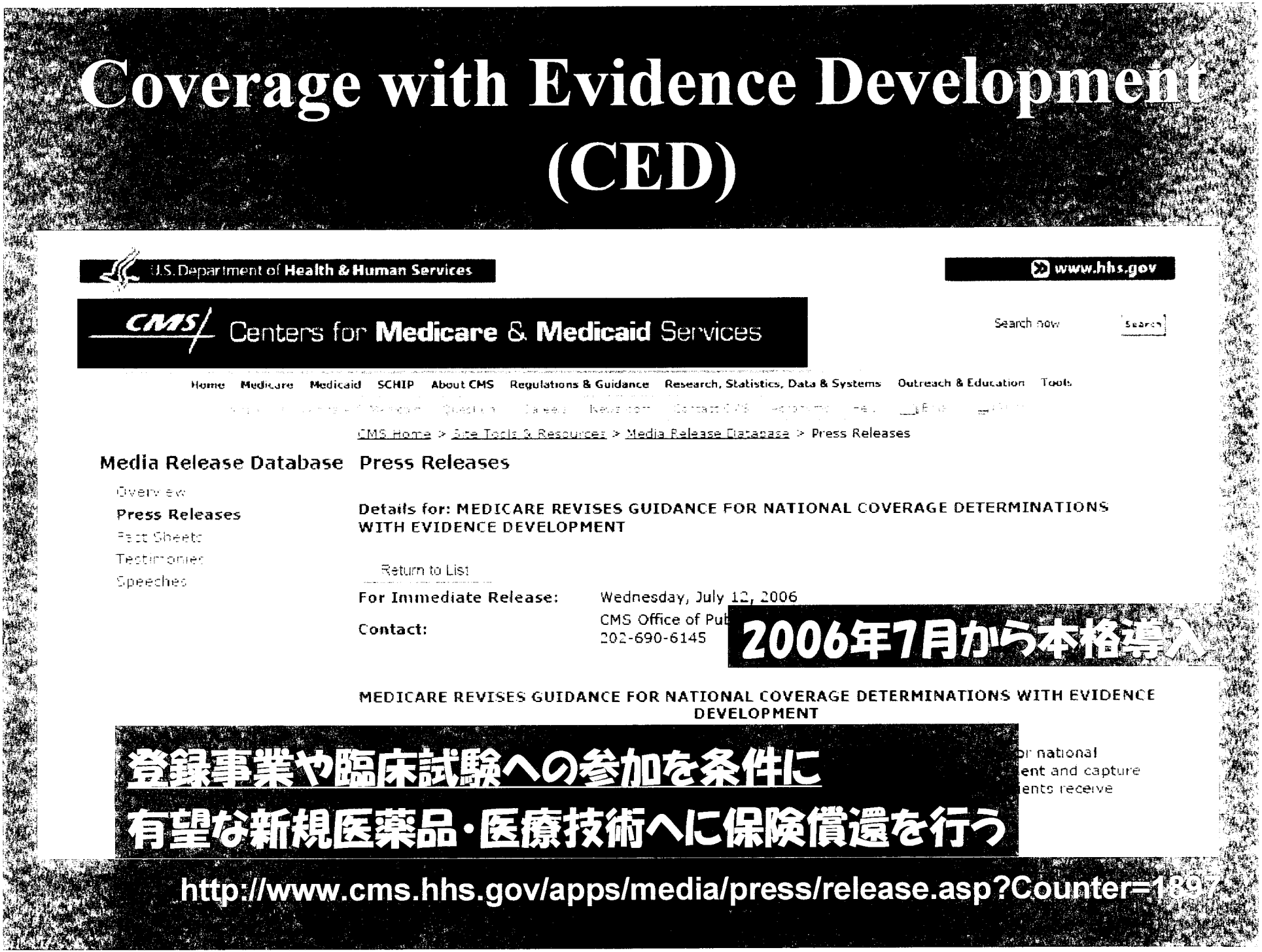
米国 臨床試験にかかるRoutine Costとは

Routine costs DO include (and are therefore covered):

- Items or services that are typically provided absent a clinical trial (e.g., medically necessary conventional care),
- Items and services required for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent),
- Items and services required for the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- Items and services that are medically necessary for the diagnosis or treatment of complications arising from the provision of an investigational item or service.

Medicare Coverage Clinical Trial Program Memorandum

Coverage with Evidence Development (CED)



EU 臨床試験指令 2001年4月公布

DIRECTIVE 2001/20/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 4 April 2001

on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in p

Having regard to the

Having regard to the Committee (2),

Acting in accordance w 251 of the Treaty (3),

Whereas:

全てのヒトを対象とする「介入的試験」に対して、
①「GCPの原則を遵守、
②倫理委員会に加えて
規制当局への届出と事前審査が義務化、
③規制当局のGCP査察実施、等

(1) Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products (4) requires that applications for authorisation to place a medicinal product on the market should be

(3) Persons who are incapable of giving legal consent to clinical trials should be given special protection. It is incumbent on the Member States to lay down rules to this effect. Such persons may not be included in clinical trials if the same results can be obtained using persons

trials required for this purpose should be carried out under conditions affording the best possible protection for the subjects. Criteria for the protection of children in clinical trials therefore need to be laid down.

規制のやり過ぎには要注意！

EDITORIAL

nature medicine

Safeguarding clinical trials

Efforts are underway to modernize clinical trial standards and normalize regulations to facilitate international collaboration. But as the European Union's Clinical Trials Directive shows, a one-size-fits-all regulatory strategy may be easier to conceive than to implement.

http://www.nature.com/naturemedicine

Nature Medicine Feb, 2007

NEWS

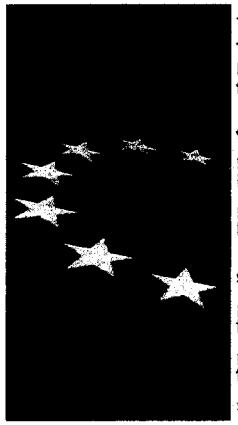
Tied up in red tape, European trials shut down

The chemotherapy drug doxorubicin has been used to treat soft-tissue cancers in children for more than 20 years, but doctors don't know the most effective dose nor how it interacts with other drugs.

In 2005, European researchers set out to find these answers in a large, multi-center trial.

Two years on, fewer than half of the 600 participants needed have been recruited. Only 2 of the 16 countries originally involved—Italy and France—began on time. Denmark has yet to start, and Poland, Austria, Sweden and Germany—the last expected to provide 25% of study subjects—dropped out. Trial coordinators canceled plans to analyze data part way through the study. The trial's 2010 end date is likely to be pushed back by at least two years.

Scientists say the study is merely the latest victim of the Clinical Trials Directive, for the Research and Treatment of Cancer estimates that expenses have risen by 85% and says the number of trials it supports has dropped by 63%. The Save European Research campaign, which represents more than 3,000 scientists, says academic drug trials have dropped by 70% in Ireland and 25% in Sweden. The number of Finnish academic drug trials shrunk by 75%.



TRIAL AND ERROR

The European Clinical Trials Directive has created bureaucratic nightmares and is shutting down trials. Since the directive's launch:

Increase in the cost of academic cancer trials in the UK	200%
Drop in academic drug trials in Finland	75%
Drop in academic trial submissions in Ireland	70%
Increase in the cost of trials supported by EORTC	85%
New trials supported in 2004 by the group	19
New trials supported in 2005 by the group	7

Sources: Cancer Research UK; *Brit. Med. J.*; EORTC

Because the directive is technically not law, "They're getting overwhelmed with the