第37回 ICH 即時報告会
ICH E8(R1)

医薬品医療機器総合機構
新薬一部　伊熊睦博
2017.12.15

経緯/背景

1997:**E6**(医薬品の臨床試験の実施の基準・GCP) 施行

E8(臨床試験の一般指針) 策定, 国内通知は1998発出.

2014-2016: **E6(R2) addendum** 追加, 2016.11 **ステップ4**.

2016 パブコメ 外部コンソーシアムからの ***open Letter***

2016.11 大阪会合：FDA提案　**戦略的アプローチ**

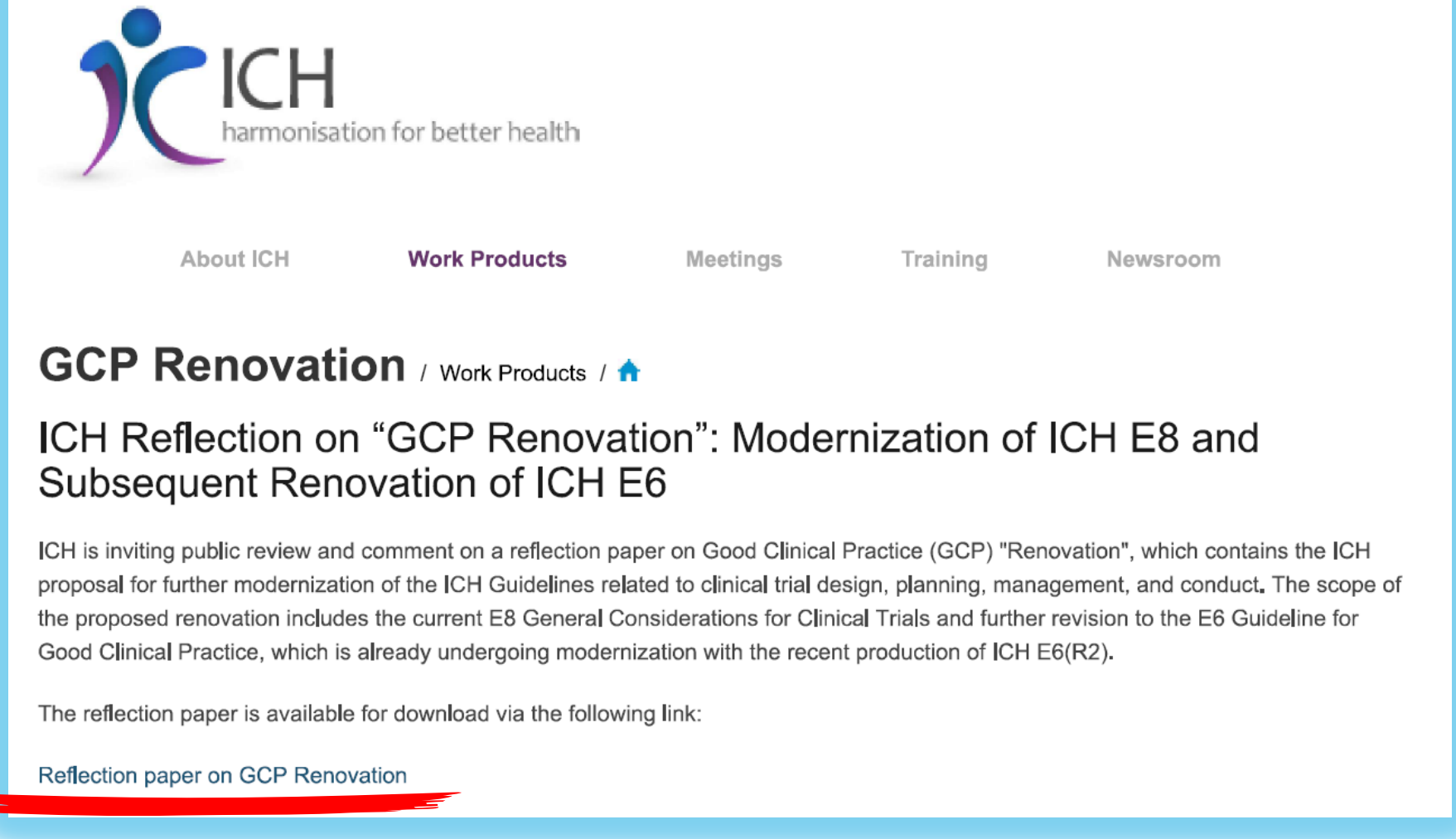
'GCP Renovation'（E8の近代化とそれに続くE6改修）

2017. 1: **Reflection Paper** 公開（+パブコメ）

2017.11 ジュネーブ: **E8(R1) IWG/EWG**

“GCP Renovation”

Modernization of ICH E8 and Subsequent Renovation of ICH E6



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GCP Renovation / Work Products /

ICH Reflection on “GCP Renovation”: Modernization of ICH E8 and Subsequent Renovation of ICH E6

ICH is inviting public review and comment on a reflection paper on Good Clinical Practice (GCP) "Renovation", which contains the ICH proposal for further modernization of the ICH Guidelines related to clinical trial design, planning, management, and conduct. The scope of the proposed renovation includes the current E8 General Considerations for Clinical Trials and further revision to the E6 Guideline for Good Clinical Practice, which is already undergoing modernization with the recent production of ICH E6(R2).

The reflection paper is available for download via the following link:

Reflection paper on GCP Renovation

Reflection paper on GCP Renovation

- E8は**GCP刷新**の全体像を描き，E6の基礎をなすガイドラインとして**大きな方針**を記述する.
- **‘Quality By Design’** の考え方の導入，被験者保護，有効性/安全性の評価の質的向上の指針を提示.
- 現行E8が示す試験デザインに関する考え方は, 医薬品の**ライフサイクル全体をカバー**する方向に．試験の多様性にも言及.
- E6では，試験タイプに応じたGCP詳細を示す**Annex追加**を提案.

- **透明性**の確保, **stakeholder**の意見聴取 ～ 等のプロセス改善も…

ICH Reflection on “GCP Renovation”:

Modernization of ICH E8 and Subsequent Renovation of ICH E6

- This paper outlines an approach to potential renovation of the ICH Guidelines related to clinical trial design, planning, management, and conduct.

- First, ICH would propose to address the broader concern about the principles of study design and planning for an appropriate level of data quality through revision to the current *ICH E8 General Considerations for Clinical Trials*. …..

- Subsequently, ICH would propose to address the flexibility concern via further renovation of *ICH E6 Good Clinical Practices* to anticipate and address a broader range of study types and data sources, …..

- Proposed Structure for a Modernized ICH E8 Guideline and a Future Renovated ICH E6 Guideline
- Proposed Plan for “Renovation” Work
- ICH Step Process Enhancement for the GCP Renovation

ジュネーブ会合での成果

- **Concept Paper** と **Business Plan** の作成/承認.

- E8 改訂に関する論点整理.
- E8 改訂文書作成の開始.

E8 General Considerations for Clinical Trials

Code	Document Title	Previously coded
E8	General Considerations for Clinical Trials	
E8(R1)	**Revision on General Considerations for Clinical Trials**	

Rapporteur : Dr. Lisa M. LaVange (FDA, US)

Regulatory Chair : Dr. Fergus Sweeney (EC, Europe)

Description : ICH is proposing a modernisation of ICH E8 in order to incorporate the most current concepts achieving fit-for-purpose data quality as one of the essential considerations for all clinical trials. The revision would propose to: identify a basic set of critical-to-quality factors that can be adapted to different types of trials to support the meaningfulness and reliability of trial results and to protect human subjects; address a broader range of trial designs and data sources; and provide an updated cross-referencing of all other relevant ICH Guidelines that should be referred to when planning clinical studies.
The modernisation of ICH E8 is the first step towards the GCP Renovation initiated in 2017.

Status : *Step 1*

Concept Paper

Business Plan

E8(R1) Experts list

Concept Paper から抜粋 (2017. 11 承認)

The revision of ICH E8 is expected to:

Since its adoption (1997) , clinical trial design and conduct have become more complex, impacting the time and cost required to develop drugs.

A wide range of both trial designs and data sources play a role in drug development and are not adequately addressed in the original E8 GL.

Approaches for optimizing trial quality, which promote the reliability, efficiency, and patient focus of clinical trials are needed.

This involves identifying the factors that are critical to the quality of a clinical trial at the design stage and planning the trial conduct proportionate to the risks to these quality factors, thereby protecting human subjects and ensuring the reliability of trial results.

Concept Paper から

The revision of ICH E8 is expected to:

- Enhance the reliability of trial results through attention to trial quality
- Better integrate overall design and planning with subject protection and data reliability considerations that are the focus of ICH E6, statistical considerations that are the focus of ICH E9, and other considerations addressed in other ICH Efficacy guidelines.
- Enhance the utility of the ICH Efficacy guidelines by including critical-to-quality factors as a key consideration in planning and design of clinical trials
- Promote the quality of trial design and conduct for a broad range of trial types and data sources with critical-to-quality factors aligned to the objectives of the trial

Concept Paper から

Strategic Importance of the Topic

This work will support improved trial design and conduct for a broad range of trial types and data sources and will promote the availability of high quality evidence.

The overall goal is to promote trials that lead to efficient and timely decision making, and ultimately to improved access to safe and effective drugs with meaningful impact on patients.

Business Plan から抜粋 (2017. 11 承認)

- It is expected that the project will begin in September 2017 and be completed by 2020.
- It is anticipated that the Step 2b will be completed by 1Q 2019 following face-to-face meetings of the EWG in November 2017, June 2018, and November 2018.
- A meeting with stakeholders will be held to discuss the step 2b document, possibly at the end of the public consultation period.
- We anticipate that Step 4 will be reached by 2020.

今後の予定

- 継続して月1～4回の電話会議

  (3-サブグループ議論, 全体会合での統合)

- 2018.6 神戸会合実施