Managing Risk: A New Tool to Ensure Site Quality Management (ISEI-PJ)

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Why we focus on Quality Management

- Need to **embed Quality Management** to site.
- Few useful tool exists to manage potential risks of **GCP violation** in Japan.
- **Risk based approach** will be stated in ICH GCP.

AS IS

Quality of risk management vary depending on sites.

- In some cases, there are many risks of GCP violation which site staffs can not identify by themselves.
- Each site has various experiences of GCP violations or similar cases and tips to mitigate and prevent it.

TO BE

Quality of risk management should be improved and shared across sites.

- Every site and staff can identify and assess the possible risks effectively and take preventive actions easily.

How we create "Risk management tool"

POINT: Any sites staff can use the tool anytime and anywhere.

※Scope is only on Japan-GCP (almost same as ICH-GCP)

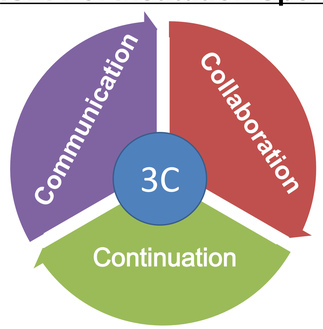
User Friendly	Assess the all risks for GCP violations only by using this tool. Assess automatically the impacts of risks according to the situation on each site.
Broad Utility	Impart knowledge on preventive actions and lessons from various experiences on other sites. Staff can revise this tool according to their demand.
FREE	Download the tool for Free on the Internet for all.

CREATING PROCESS

- Brain storming=>**400 examples** are identified by 3 months.
  "What violation can occur depending on each GCP's items"
- 400 examples are categorized into **154 types** by 2 months.
- Prioritize each example by Impact, Probability and Detectability.
  - Impact: High(H), Middle(M), Low(L)
    H: Impact to safety for subject, M: Other, L: No impact to safety
  - Probability and Detectability : High(H), Middle(M), Low(L)

Who is ISEI-PJ

ISEI-PJ: Institution Sponsor Efficiency Improvement Project



Working Group for improving Efficiency of Clinical Trials in Japan.

Various members from Sites and Sponsors

31 Members from various Sites and Sponsors

i.e. Pharma co., CRO, Academia, pre-Regulatory authority, Medical center

Everyone has participated voluntary for 5 years.

Deliverables: Work shops, useful tools for site staff and sponsors.

- Annually FREE Work shop (Source data/documents identification, Electronic document, ICH-GCP, RBM, millstone payment)
- Site selection～Closure check list

Easy to ask questions by e-mails and F2F.

What is and How to use "Risk management tool"

SIZE A4 10 papers

COST FREE download

QUALITY FULL covering of GCP

FLOW

Check Yes or NO to the Question in Risk factor detail → Prioritize these items according to the Impact, Probability and Detectability. → Take preventive action according to the mitigating action.

Home Page

Category	Check	Risk factor	Risk factor detail	Impact	ICH-GCP	Issue statement	Mitigating action
Records (IRB/IEC)	☐Yes ☐No ☐NA	Retain relevant records properly	Documents are not retained for the recommended periods.	H	3.4/4.9.5	The documents aren't available upon request from the regulatory authority(ies). Lose documents by mistake when the system to storage e was changed.	Pay more attention if the documents are staged for periods especially when IRB was outsourced. Need to well organize to be available upon request especially when the storage was outsourced.
Resources	☐Yes ☐No ☐NA	Adequate Resources	Staff are changed frequently.	M	4.2.3/4.2.4	Not to be able to keep the adequate number of staff for the foreseen duration of the trial because the site staff changed frequently.	Need to secure the root to know such information and to organize to assign the other staff as soon as possible when know such information especially for important staff. Make some hand over process to equalize and validate the assessment.
Investigational Product(s)	☐Yes ☐No ☐NA	Storage Investigational Product at adequate condition	Not well organized to check the temperature excursion	H	4.6.4	Prescribe the Investigational Product(s) in temperature excursion not to aware it even if recording the storage temperature.	Make system not to prescribe the IP when the temperature excursion. Double check the temperature by system and manual. Prescribe the timing to check the temperature by manual.

Discussion

- There are **many differences in prioritization between sites and sponsor staff.**
  - Different impact for about 50% of examples.
  - Sponsor focus on the study Quality while Site staff focus on clinical Quality .
- The discrepancies in prioritization help us to **understand deeply what GCP states by discussing.**

Result

- **Very Efficient** to assess risk and take preventive action.
  - This tool can find unpredictable risk by checking all items.
  - Staff are more confident in their Quality when few risks exist.
  - We can take preventive action smoothly by referring tips.
- **Very useful** to train junior staff about GCP deeply.
- **Very meaningful** to discuss this tool for sponsor and site staff from different points of views.

Future Plan

Short-term Goal : Upgrade this tool

- To improve the way of prioritization by adding "probability detectability".
  *Automatically judge the risk as Critical or Major or Minor via the points

Long-term Goal : Adding new value to this tool

- By assessing the efficiency for training to new staff.
- By adding items for checking the Sponsor's risk
- By migrating the tool to categorize according to ICH-GCP.

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