10th Joint Conference of Japan and Taiwan on Medical Products Regulation

Digital Tools In Clinical Trials

Current Utilization Situation and Challenges In Taiwan

20 October, 2022

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衛生福利部 食品藥物管理署 Taiwan Food and Drug Administration

Outline

- Introduction to Digital Clinical Trial
- Digital Site Activation & Recruitment
- Digital Health Data Collection
- Future Prospects

During COVID-19 Pandemic…

Return visit of trial participants

- Sponsors should evaluate COVID-19 impact on conduct of clinical trial and make the amendment of protocol.
- Sponsors must follow the procedure approved by IRB of original site if transferring the trial participants to another qualified site approved by TFDA.

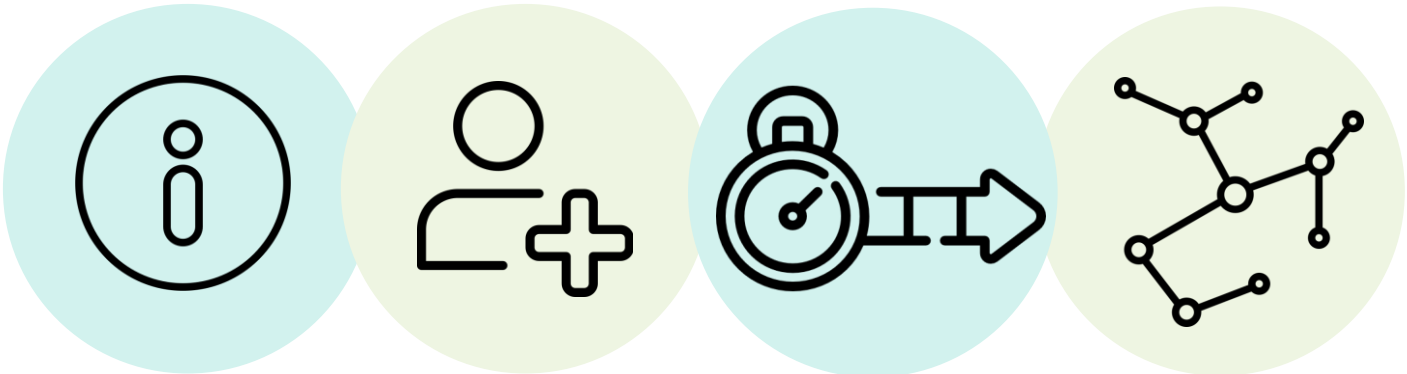
Administration of Investigational drug

- Administration and delivery of Investigational drug should be in compliance with Pharmaceutical Affairs Act and GCP.
- Trial participants could access investigational drugs delivered by authorized study nurse or by the logistics company qualified for GDP.
- Establish standard protocol for administration and delivery of investigational drugs, and record all works for inspections.

Reports of SAE and protocol deviations

- To assure right of trial participants and maintain quality of trial, TFDA recommend that sponsors and investigators report any SAE and deviation as per protocol.

Limitation of Traditional Clinical Trials



Information not easily accessible

Poor compliance

Long timeline

Limiting the diversity of participants

e.g. only about 8% of cancer patients enroll in cancer trials

Decentralized Clinical Trials (DCT)

Fully Decentralized

- **All conducted virtually**
- Enable by digital technologies
- Supply delivery

Hybrid

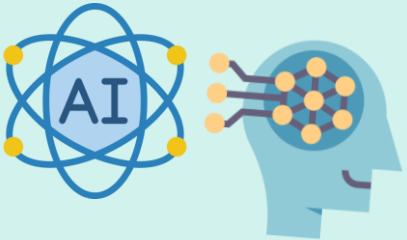
- **Complex procedures** (Injection, Cell therapy, MRI…) at a research site or local hospital
- **Less complex procedures** (Vital sign, ECG monitoring …) via telehealthcare, remote data collection, and direct-to-patient therapy

Fully Centralized

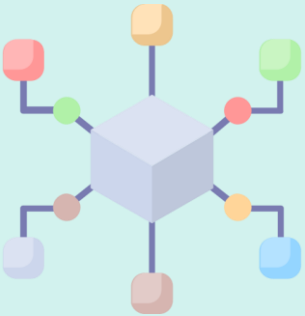
- **All conducted at a research site**

Emerging Digital Tools May Help

Real World Data Analysis

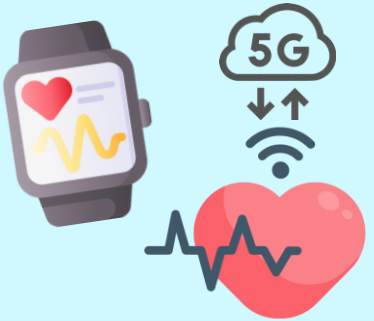


Artificial Intelligence
Machine Learning



Blockchain

Real-time Data Capture



New Digital
Health Technology

Remote Operation

Electronic Reports & Telemedicine

Digital Health Technologies in DCT

Site Activation	Digital Recruitment	Digital Data Collection	Digital Analytics
• Remote site monitoring • E-submission to HA/ethnics	• Social media engagement • Electronic informed consent	• E patient report outcome • Electronic data capture • Software as a medical device • Remote patient monitoring • Telemedicine • Real world data/real world evidence	

*COA= Clinical Outcome Assessment; PRO= Patient Reported Outcome

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E-submission to TFDA & IRB

TFDA

MRCT cases were required to be submitted by ExPRESS system since 2020.

All clinical trial cases needs to submit using the ExPRESS system since 2023 .

2020/5/26

COVD-19 Outbreak

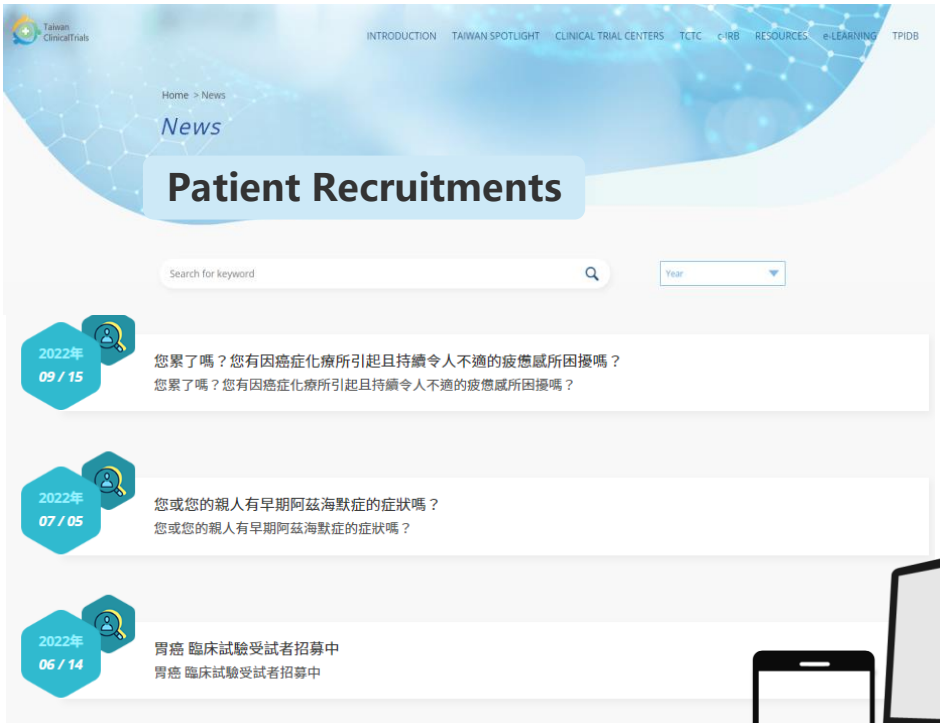
2023/1/1

IRB

IRB have their own protocol tracking & management systems (PTMS).

* ExPRESS= E platform for Review & Submission MRCT = Multi-Regional Clinical Trial

Social Media Engagement



Ref.: https://www.taiwanclinicaltrials.tw/tw/news/3

Vaccine Trial Recruitment Platform

中文版 English

- 本平台是因應新冠肺炎防疫所需，加速疫苗臨床試驗進行，以支持國內新冠肺炎(COVID-19)疫苗研發。
- 如您有意願參與COVID-19疫苗臨床試驗，請您點選「我要登記」，詳細閱讀意向書資訊並填寫相關表格。於確認資料正確無誤後，提交予本平台。平台將自動發送通知至您的電子郵件信箱，請開啟登記確認信並點選連結，以完成登記。
- 未來可能有疫苗研發廠商或試驗機構依您提供之資訊主動聯繫您。屆時您可選擇參加，亦可拒絕，將不影響您的任何權益。

我要登記　取消登記

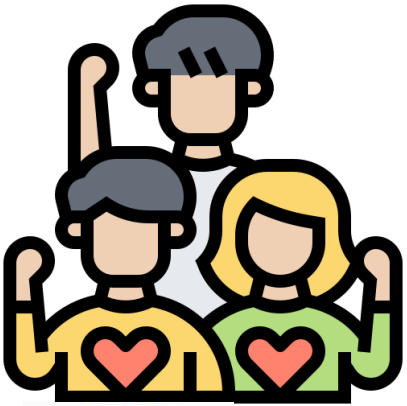
諮詢電話
1922、1919

民眾版QA　懶人包

More than 10,000 people registered on the 1st day. More than 30% patients in the trials were from the recruitment platform!

Recruitment Platform of Hospitals

Health Volunteer Recruitment Platform



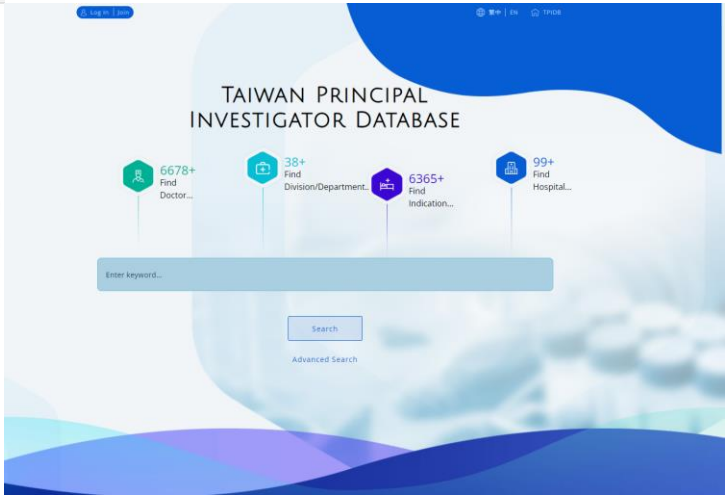
成大醫院　三軍總醫院　高醫

Taiwan Clinical Trial Database

- Patients and sponsors can find…

Find a Trial

Find a Doctor/Indication/Hospital



Database from ExPRESS

E-PRESS FDA E Platform for Review & Submission

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Electronic Informed Consent

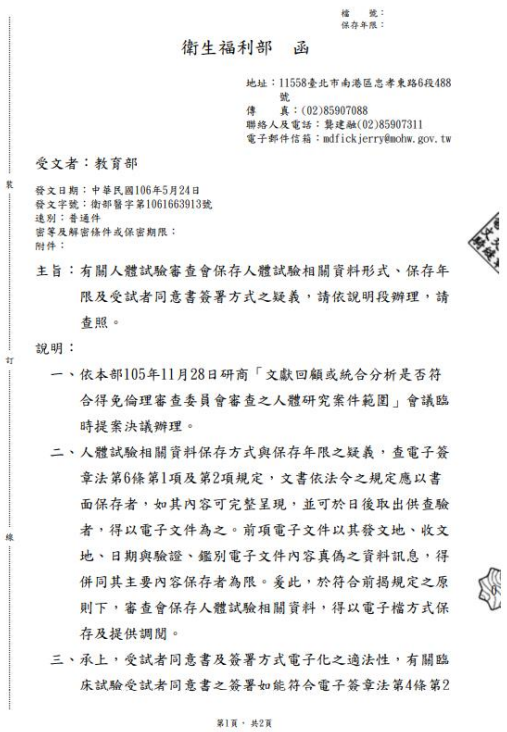
Better Comprehension

Improved Recall of ICF

Increased Adherence

Reduced Drop-out Rate

Electronic Informed Consent



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發文日期：中華民國106年5月24日
發文字號：衛部醫字第1061663913號
速別：普通件
密等及解密條件或保密期限：
附件：

主旨：有關人體試驗審查會保存人體試驗相關資料形式、保存年限及受試者同意書簽署方式之疑義，請依說明段辦理，請查照。

說明：

一、依本部105年11月28日研商「文獻回顧或統合分析是否符合得免倫理審查委員會審查之人體研究案件範圍」會議臨時提案決議辦理。

二、人體試驗相關資料保存方式與保存年限之疑義，查電子簽章法第6條第1項及第2項規定，文書依法令之規定應以書面保存者，如其內容可完整呈現，並可於日後取出供查驗者，得以電子文件為之。前項電子文件以其發文地、收文地、日期與驗證、鑑別電子文件內容真偽之資料訊息，得併同其主要內容保存者為限。爰此，於符合前揭規定之原則下，審查會保存人體試驗相關資料，得以電子檔方式保存及提供調閱。

三、承上，受試者同意書及簽署方式電子化之適法性，有關臨床試驗受試者同意書之簽署如能符合電子簽章法第4條第2

第1頁，共2頁

Restriction

According to **§ Medical Care Act/ § Human Subjects Research/ § Act for Good Clinical Practice**

"…When conducting human research, medical care institutions shall … first obtain a **written consent from** the research subjects …"

Requirement for eSignature

- With the consent of the subject
- Information presented in its integrity
- Remain accessible for subsequent reference

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Digital Health Data Collection

EMR

- Patient assessment
- Connect to NHI cloud systems

IXRS

Screen / randomize subjects

ePRO

- E-Questionnaire
- E-diary
- AE/SAE report

Wearable/ Mobile Device

Monitor participants' condition

EDC

Data entry and collect

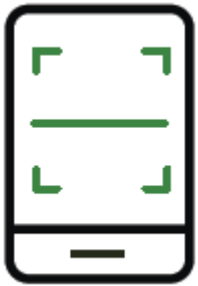
Central lab

Specimen control and inspection

* EMR= Electronic Medical Record/PRO= Patient Report Outcome/EDC=Electronic Data Capture

ePRO Example

- Follow up the adverse events after COVID-19 vaccination:



01

Scan the QR code at the vaccination site to key in the time of vaccination.

02

Read and agree to personal confidentiality agreement

03

Key in basic information in Taiwan CDC official Line account

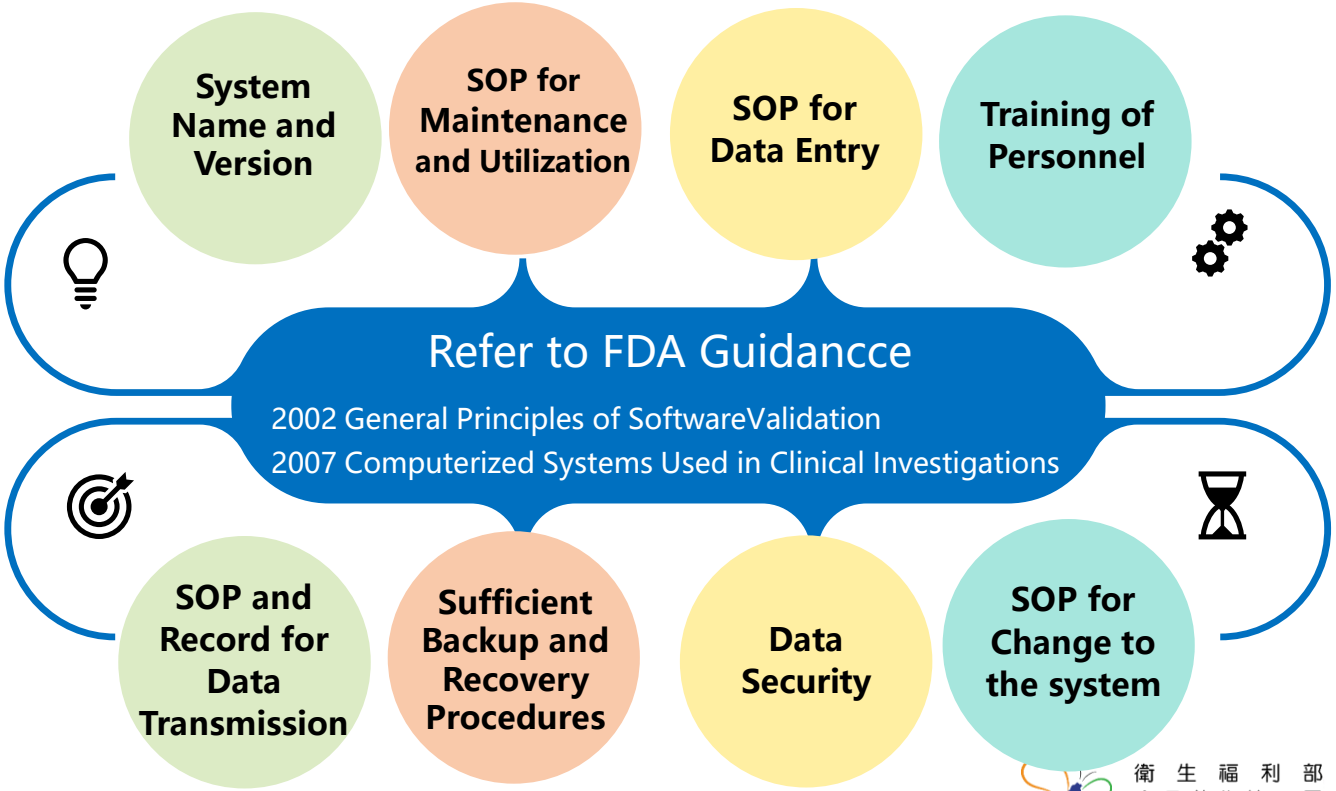
04

Be notified by Line account to key in the health condition

Reference: Taiwan V-Watch COVID-19疫苗接種-健康回報 - 衛生福利部疾病管制署 (cdc.gov.tw)

Clinical Trial Management System

Key Points for Computerized Systems in GCP inspection



Remote Monitoring (NCKUH)

Before Monitoring

- Contact the Clinical Research Nurse (CRN) and book the date of remote monitoring.
- Sign the confidentiality affidavit.
- Limited to EMR, clinical trial pharmacy documents and clinical trial materials in paper should be monitored on site

Monitoring

- Use Cisco Webex meeting software, Log in to the EMR screen operated by CRN, and lock the screen.
- Turn on the 2 video cameras and video record in software all the process with no background graphic.
- Paper medical records or other paper documents are not yet available for remote monitoring.

After Monitoring

- After the monitoring is over, the clinical trial center team will review the recording of the meeting according to the "Personal Data Security Management Procedures " on the same day.

Challenges of Remote Inspection

Postponed on-site inspections during COVID-19 pandemic

Prioritized domestic on-site inspections: **COVID-19 vaccines**

Conducted 2 partial remote inspections

Facility tour of pharmacy via video

- Technological problems: sound is not clear, volume is too low, audio latency…
- The amount of time would be increased: preparation of equipment, inefficient communication

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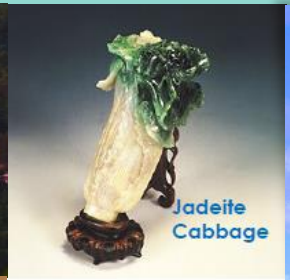
Future Prospects

Consolidate international regulations and develop guidance on DCT/digital tools (e.g. FDA/EMA guidance)

Develop clinical trial systems (Ex. clinical trial recruitment platform)

Mock Remote GCP inspection

Government Resources Integration (e.g. department of medical affairs)



THANK YOU !

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