受查核經驗分享 -從試驗委託者角度

臺灣阿斯特捷利康
CLINICAL QUALITY ASSOCIATE DIRECTOR (CQAD), SITE MANAGEMENT & MONITORING

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114.06.11

TFDA查核制度新增重點

1997

- GCP site inspection established
- Closeout CSR submission triggered

2001

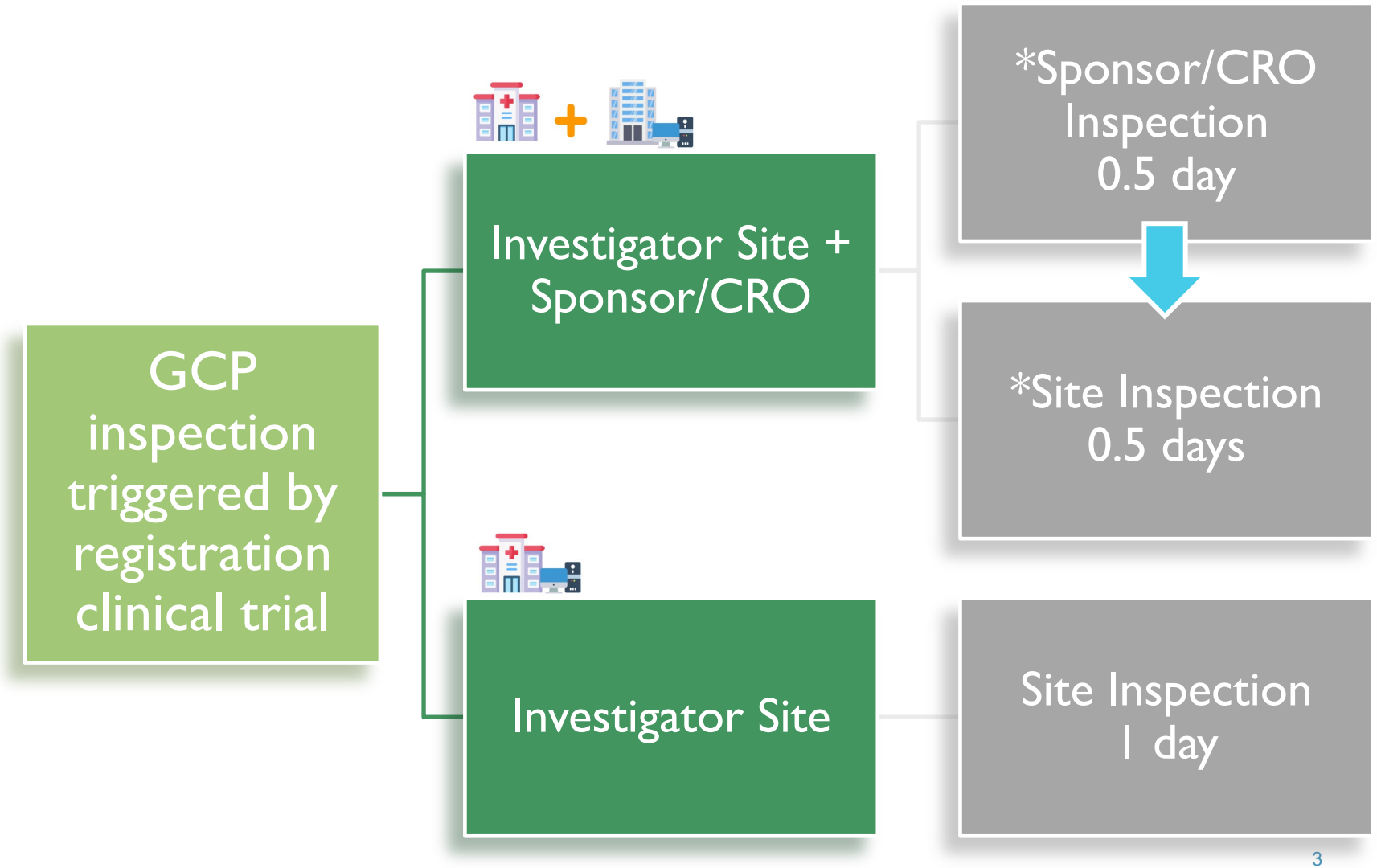
- NDA and CSR submission triggered
- Site inspection from 0.5 to 1-day

2024

- Effective since 01Jul2024
- NDA, **sNDA**, and CSR submission
- **Sponsor(CRO) + site (2x 0.5 day) or site inspection (1 day)**
- **Sponsor data management request** within site inspection scope

GCP查核的對象與天數

- 廠商與試驗機構，原則上各半天
  0.5-day inspection on different days
- 先查委託者**/CRO**，再查試驗機構，傾向一週內完成
  Sequential Sponsor/CRO and Site Inspection (generally within 1 week)



GCP查核重點相關公告參考文件:

- 強化藥品臨床試驗GCP查核與藥品查驗登記審查連結精進方案(113年1月公告版)
- 「強化藥品臨床試驗GCP查核與藥品查驗登記審查連結精進方案」問答集(113年1月公告版)
- 藥品臨床試驗查核紀錄表(V10.0)_自行查核填寫範例及說明_版本：113.06
- 試驗申請須知(十六)申請藥品臨床試驗報告備查案應檢附資料
- GCP查核併藥品查驗登記申請案之臨床試驗資料表**(NDA送件時繳交)
- 藥品臨床研究專員(CRA)職能訓練指引
- 113年度藥品臨床試驗GCP查核說明會:113.5.30

評估新制查核重點與應變對策
COUNTRY RISK ASSESSMENT & MITIGATION PLAN (I)

查核新制新增的重點內容?
What is new?

是否有對應之備查資料?
Mitigation plan?

Sponsor組織架構與人員相關	因應對策
組織架構/人員授權與管理	彙整各相關部門組織圖，試驗管理SOP清單
CRA職能訓練指引: GCP時數、SOP	統整教育訓練時數清單 & 撰寫Taiwan SOP

評估新制查核重點與應變對策
COUNTRY RISK ASSESSMENT & MITIGATION PLAN (II)

查核新制新增的重點內容?
What is new?

是否有對應之備查資料?
Mitigation plan?

試驗管理相關查核重點	因應對策
試驗監測 、稽核、品質保證系統	SOP、監測計畫、QA稽核計畫、Mock Interview
電腦資訊系統與數據管理	系統授權(合約)、數據管理計畫 、Data Flow/SME

*QA: Quality Assurance (品質保證)
*SME: Subject Matter Expert (領域專家)

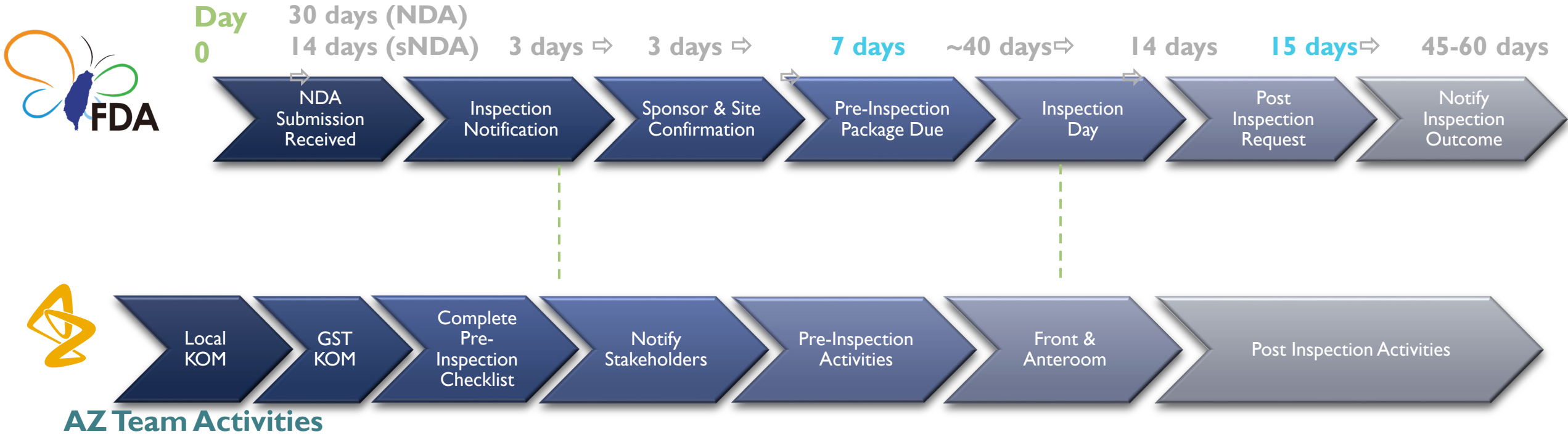
評估新制查核重點與應變對策
COUNTRY RISK ASSESSMENT & MITIGATION PLAN (III)

查核新制新增的重點內容?
What is new?

是否有對應之備查資料?
Mitigation plan?

Supplier/IMP相關查核重點	因應對策
第三方授權(包括CRO)	確認Global/Local Vendor 管理計畫與合約
試驗期間試驗藥品、醫材、儀器流向	彙整進口、使用、銷毀 或退運文件備查

TFDA INSPECTION TIMELINE



台灣法規部門送件預定時程之2-3個月之前啟動TFDA查核文件準備

強化精進方案新制之後的查核經驗

STUDY-01
Solid Tumor

- Scope: **Sponsor + Site Inspection**
- Date: Nov2024 (two half days)
- Trigger: **NDA submission**
- Internally Led (Alliance RA submission)
- Local Inspection Tracker
- **TW AZ first sponsor inspection**
- **Global SMEs: QA, Global team, DM**
- Outcome: No major finding; recommendations shared

STUDY-03
Hematology

- Scope: Site Inspection
- Date: Feb2025 (1 full day)
- Trigger: **sNDA submission**
- Internally Led
- Digital Tool, **DM SME**
- Outcome: No major finding; recommendations shared

STUDY-02
Hematology

- Scope: Site Inspection
- Date: Dec2024 (1 full day)
- Trigger: **sNDA submission**
- **Outsourced to CRO**
- ***Taiwan AZ local SMEs participated***
- Digital Tool, **DM SME**
- Outcome: No major finding; recommendations shared

STUDY-04
Solid Tumor

- Scope: Site Inspection
- Date: Mar2025 (1 full day)
- Trigger: **sNDA Submission**
- Internally Led
- Digital Tool, **DM SME**
- Outcome: No major finding; recommendations shared

More Potential Inspection Activities

- More under planning of RA submission : **5+ in 2025**

[加強重點準備策略]

Data Management

- Prioritize study DM SME to stand-by (Asia time zone)
- Checklist and DM/stats/study management documents are supported by Global Study Functional Team

Global and Local Awareness

- Continuous Training on Lesson Learned
- Internal Tool/Insight to Identify Potential Study/Site based on TFDA selection strategy

IMP

- Photograph of IP and Label in Local Language should be retained as early as possible
- Reconcile and Cross-check IP shipment & CoA/Batch Record

CRA Training

- SOP and tracking of CRA training per TFDA guidance
- Continuously hold internal training sessions
- CRA Mock Interview

[試驗委託者的經驗重點]
KEY TAKEAWAY FOR TFDA INSPECTION

Sponsor Request

對相關部門廣為宣傳
TFDA查核的重要性

Global team, DM & QA

請求國外支援查核

Anticipate RA timeline to Start Early

追蹤法規單位送件時程
提前規劃

Know What's Expected, Prepare Well, Be Ready!

熟讀公告表單與說明會
資訊，以利充分準備

[未來規劃建議]
FOR TFDA CONSIDERATION

Site vs Sponsor 分開查核

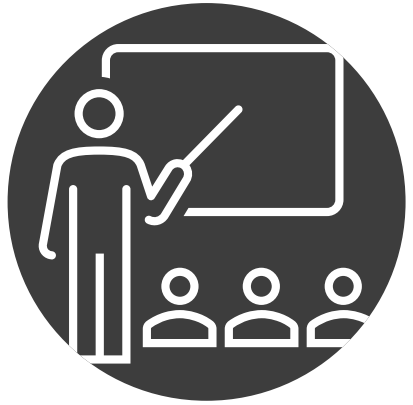
- 建議僅在委託者查核中檢視sponsor試驗管理文件
- Sponsor查核可採遠距文件查核，以網路視訊安排面談
- Site 查核紀錄表回歸僅需填寫隸屬試驗機構之項目

查核委員 查核項目明確分工

- 查核紀錄表各大項目有主責委員
- 減少多位委員同時要求同一份文件

宣導試驗機構 配合與協助項目

- 空間，時間，人力
- 一日查核需代買委員午餐



強化查核紀錄表填寫 說明與範例

- 不同委員對檢核表填寫詮釋應一致
- 加強說明範例
- 年度分享常見填寫錯誤

THANK YOU!