

Internal monitoring of screening data by trial sponsor: the case of US-funded Prime-Boost HIV Vaccine Phase III Trial Thailand

Prime: ALVACCP1521 (sanofi pasteur)
Boost: AIDSVAX® B/E (VaxGen Inc.)

Suchada Chinaworapong

Infrastructure



Chon Buri :

district 4: Bang Lamung

5: Pan Thong

7: Siracha

9: Sattahip



Rayong :

district 1: Mueang Rayong

2: Ban Chang

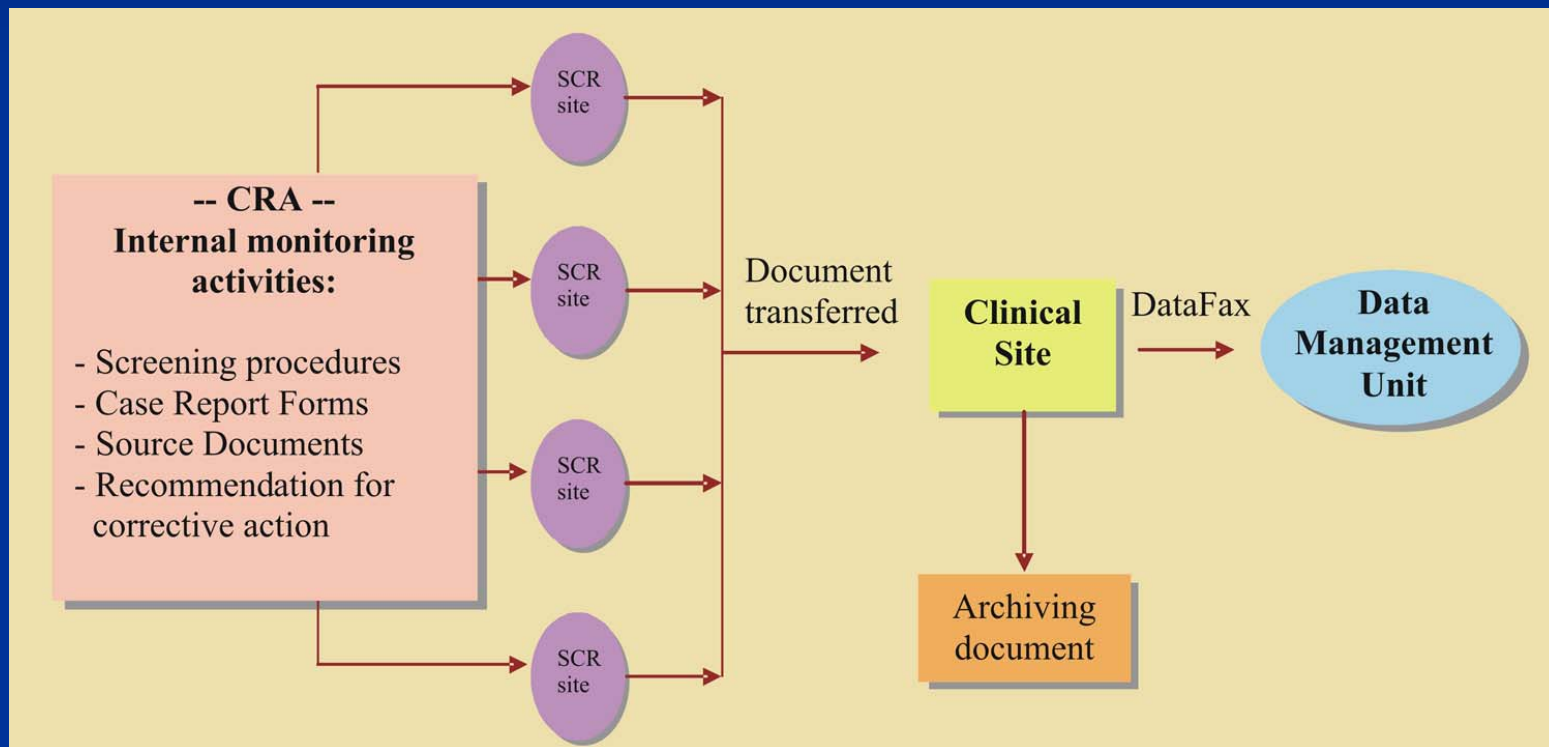
3: Klaeng

5: Ban Khai

- Four districts / province
- One CRA / district
- Three to seven screening sites / district
- Two staff / screening site
- Three CRFs and ten source documents / screening volunteer
- 26,676 cases were screened

Total: 8 districts, 47 screening sites, 10 CRAs, 141 screening staff, 79,700 CRFs and over 266,760 source documents

Document Flow



Conclusion

- Internal monitoring as an adjunct to formal monitoring by the trial sponsor is useful in the setting of large, community-based trials.
- Monitoring SOPs and clear Terms of Reference.
- User-friendly design for all documents to be used by staff.
- Regular meetings for sharing critical observations and providing continuous training for both screening staff and clinical trial monitors.

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 - Ministry of Public Health
 - Armed Forces Research Institute of Medical Sciences, Thai and US components.

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