

Electronic Data Capture in an Academic Research Organization

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Society for Clinical Trials
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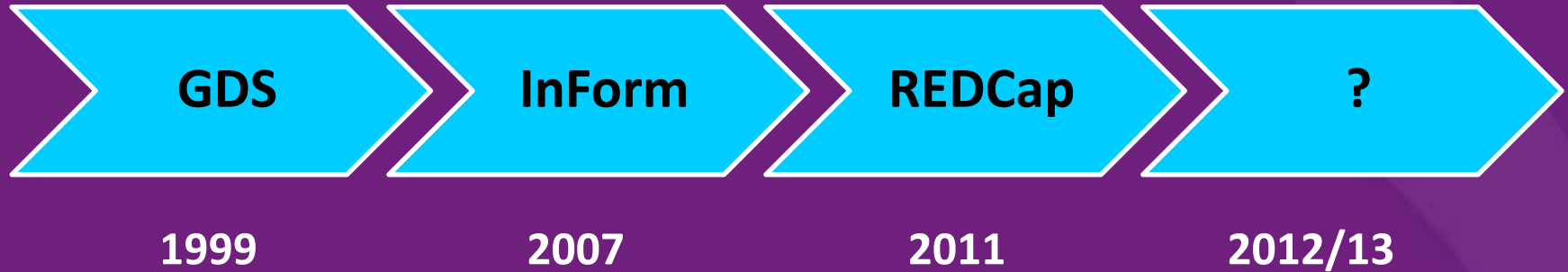
The George Institute for Global Health

- Not-for-profit ARO
- Funds from NHMRC
- Offices in Sydney, Beijing, Hyderabad and Oxford
- Cardiovascular, renal, neurological, critical care, musculoskeletal and injury
- Large-scale national and international projects
- Clinical trials, surveys, observational cohorts
- Commercial arm

Data Management

- Data Management division
 - 13 employees ((S)DMs, programmers, DBA) in Sydney and Hyderabad
 - Mostly large-scale clinical trials and cohorts
 - CRF design, database setup, reporting, cleaning, coding, etc.
 - eDC only (no paper)
 - GDS and InForm
- Research divisions
 - Smaller projects
 - Research fellows and PhD students
 - Mix of paper and electronic
 - REDCap and other

EDC history



	GDS	InForm	REDCap*
+	Free Flexible	Feature-rich Industry standard	User-friendly Free
-	No GUI for build Difficult to setup Training	Expensive Complex Support	Not commercial No query module
<i>Best for:</i>	<i>Study needing a flexible solution and with sufficient time for setup</i>	<i>Study needing standard complete solution and with appropriate funding</i>	<i>Academic study with limited funding Observational studies</i>

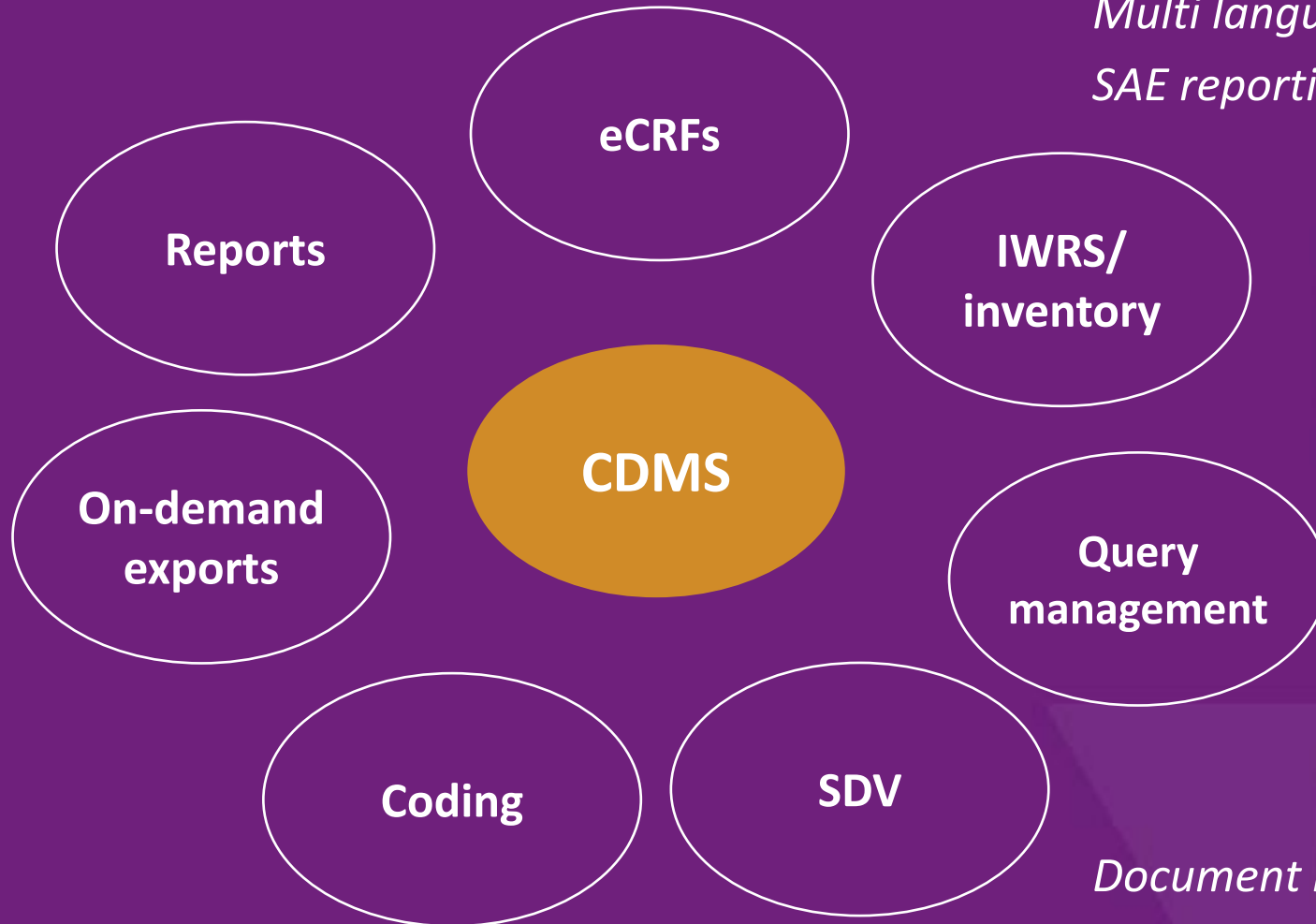
* Assuming randomization available

Case studies

1. CHEST
2. Commercial CVD trial
3. Lisa's trial

Desirable eDC features

Lab uploads
Adjudication
Multi language
SAE reporting



Document Management
Site Payment
Paper Trials
Offline

REDCap

OpenClinica

InForm

Features

Document Management	✔	Document Management		Document Management	✔
ePRO		ePRO		ePRO	
Randomization		Randomization		Randomization	✔
Inventory Tracking		Inventory Tracking		Inventory Tracking	✔
Ad-Hoc Reporting	✔	Ad-Hoc Reporting	✔	Ad-Hoc Reporting	✔
Safety		Safety		Safety	✔
PDF Archiving		PDF Archiving		PDF Archiving	✔
On Demand Export	✔	On Demand Export	✔	On Demand Export	
Lab Values/Ranges Management		Lab Values/Ranges Management		Lab Values/Ranges Management	✔
Multi-Language	✔	Multi-Language	✔	Multi-Language	✔
Site Payment		Site Payment		Site Payment	
Paper Trials	✔	Paper Trials	✔	Paper Trials	
Offline		Offline		Offline	✔
Medical Coding		Medical Coding		Medical Coding	✔
EHR Integration		EHR Integration		EHR Integration	

CDISC Certification

Certified version: Not Certified

Certified date: --

Certified version: Not Certified

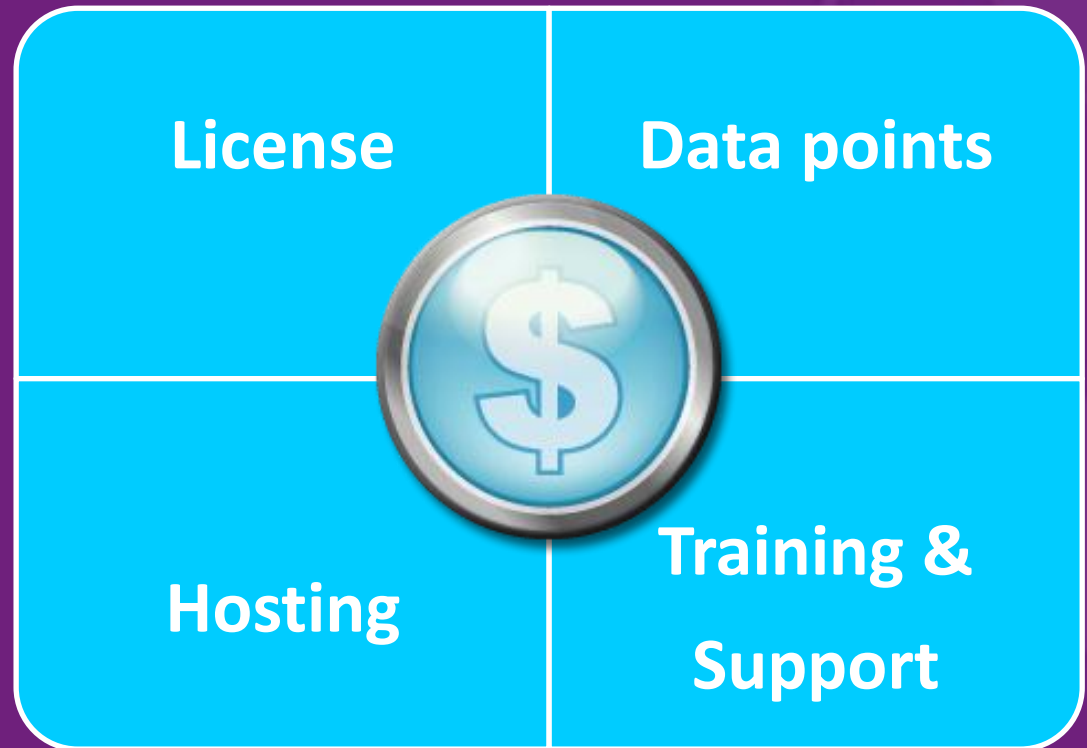
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Certified version: 1.3

Certified date: 2008-11-26

(other) things to consider

- Ease of setup
- Ease of use
- Hosting
- Outsourcing
- Commercial?
- Support
- Integration
- Compliance
- **Cost**



Summary

- Variety → multiple systems
- Cost main limitation
- Compare and test features
- Flexibility + simplicity
- Consider REDCap

References

- www.thegeorgeinstitute.org
- Tyson G, Dietlin T. Realizing the Promise of Electronic Data Capture. A practical guide. Campbell Alliance white paper.
- <http://project-redcap.org/>
- <http://edcmarket.appspot.com/>