Course recognition - suggestion

- The following institutions support and recommend this course to research teams and others interested in learning the fundamentals of data management

Study requirements to consider when selecting a CDMS

- Will the data need to be submitted to regulatory authorities such as FDA for possible registration?
- Coding dictionaries e.g. MEDdra (licensing)
- National and other regulatory requirements/guidelines such as
  - CFR 21 Part 11 for the United States
  - Directive 2001/20/EC for the EU countries
  - ICH GCP and GCDM
  - POPIA (Protection of Personal Information Act) RSA - 2013

Why to we have these DM regulations

- An article 'Science and serendipity' in Clinical Medicine 2007 Dec;7(6):562-78. :
- 'The terrible cost of vaccine scares is well documented and should have engendered more appropriate rigour and caution among those promulgating and publishing this one. ... Despite assertions to the contrary by the MMR scaremongers, measles is also not a trivial condition.
- It maims and kills a small, but not insignificant, proportion of children in developed countries.
- In the Netherlands outbreak of 1999–2000, **3,250 cases of measles were notified, 97%** of which were in the **unvaccinated Dutch Reformed community, around 20% had serious complications, including five cases of encephalitis and three deaths.**
- In the Irish outbreak of 2000, which occurred as a direct result of lower vaccination rates following the MMR scare which reduced coverage to just 74%, there were 1,500 notified cases and three deaths.

History of validation

- Proposed by the FDA in the early 1970s
- The need was driven by several large scale problems in the design of design of products
- EG. Therac-25 incident

Suggestions - Choosing a DM system (a)

- Microsoft Access can be programmed to meet all requirements of a Clinical Data Management System (CDMS).
- However this is a massive task that will involve system development and test teams to create the necessary functionality and security mechanisms.
- The costs and effort would be similar to that of building a CDMS using any other database such as SQLServer or MySQL which have more robust database engines than Access.

Under choosing a data management system (b), delete the bit from 'The EpiHandy software ...'

- OpenClinica have recently announced the release of OpenClinica Participate which is a smartphone app aimed at participants doing their own data entry (ePRO).
- As such, it may be suitable for use by CRWs that are 'smartphone literate' in remote areas provided there is mobile network coverage at reasonable cost

And.. At the bottom of the page

- The requirements are exacting, but are necessary to meet the requirements that the data is accurate, complete and cannot be repudiated.

Suggestions – Data archiving

- It is a requirement of the various regulatory bodies that all original source documents are saved (archived) for a number of years - the number depending on the type of study and the regulatory body.
- Typical values range from 2 years to 10 years. Source documents include not only CRFs, but also x-rays, ECGs, lab results etc. They must be saved in a secure and fire-proof environment and must but well indexed and documented to enable subsequent retrieval of specific documents.

Data archiving

- Electronic data (which includes and e-source data as well as the data stored in the CDMS) must be copied onto a secure medium such as CD/DVD and archived.
- The data must be saved in 'human-readable' form. This implies that it is not sufficient to save a copy of the locked CDMS database as this is not human-readable, and the accessibility of the data is dependent on the CDMS still being available, and capable of reading the archived data.
- For instance MS Access introduced a new format .accdb with Access 2007. It is quite possible that the older .mdb format will not be supported for much longer.

Data archiving

- To meet the human-readable requirement, some CROs generate a pdf copy of every eCRF that was captured or imported into the CDMS. While this meets the requirement, it would be very difficult to establish a copy of the data should a subsequent study wish to make use of it.
- A better approach (which is supported by OpenClinica) is to export the data in XML format and save this to CD.
- The data should ideally be exported in CDISC compatible form, as this would allow it to be imported into any database that supports CDISC.

Other, might be nice?

- Check list for essential to included for each section?
- 5 point checklist to complete for mandatory DM tasks?
- Link to useful URLs? EG WWARN data archiving check list?