National Mutual Acceptance (NMA) policy development for teletrials

May Workshop 2019

Streamlining Clinical Trials and Research

10 years in Victoria

NMA

Established in November 2013 for multi-centre clinical trials

Single ethics review for multi-centre research across jurisdictions

December 2015 the scope was expanded to all multi-centre research projects

Mutual acceptance of teletrials under NMA

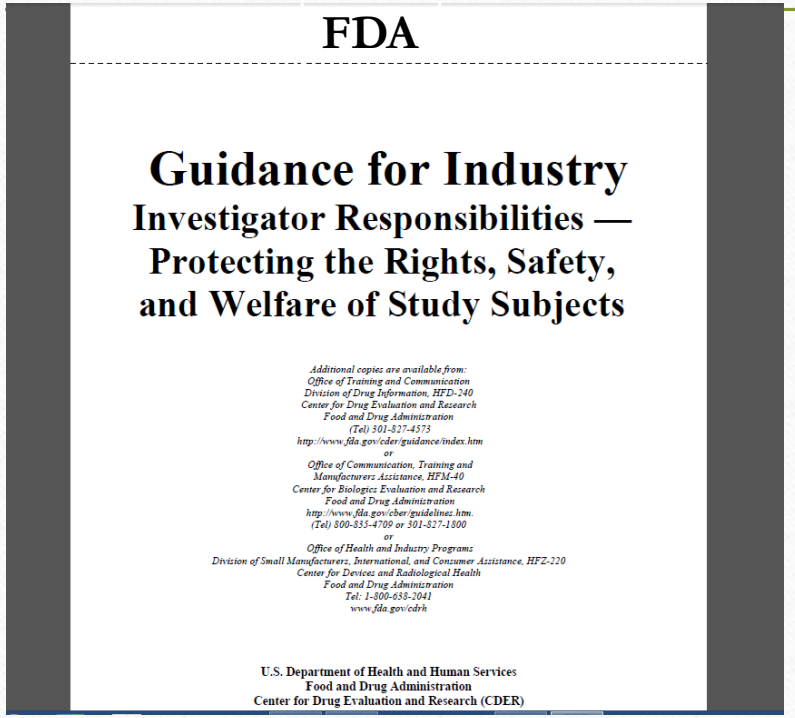
- Questions raised regarding teletrials and multi-centre clinical trials

	Multi-centre	Teletrials
Clinical Trial Research Agreement	Medicines Australia CTRAs between Institution and sponsor	Head agreement (CTRA) at primary site Sub-contract between primary site & satellite site
Insurance /Indemnity	Medicines Australia – commercially sponsored trials Jurisdiction insurers provision for Investigator Initiated trials	Medicines Australia 'Head' agreement for commercially sponsored trials Investigator Initiated trials – jurisdiction insurers to advise

Mutual acceptance of teletrials under NMA

	Multi-centre	Teletrials
Regulatory requirements Clinical Trial Notification (CTN) or CTX	Site based Sponsor pays a fee per site	Satellite not a separate site under CTN/CTX
Supervision plan/s	CPI responsible overall for the study Supervision Plan: CPI and site PIs	PI responsible for the Supervision Plan at primary and satellite site/s
Site –Specific Assessment (SSA)	Site responsibility & authorisation Site fee	Primary site and satellite site SSA authorisation – fees (local policy)
Recruitment/Consent	PI and study sites responsibility	Primary site PI responsibility: recruitment potential, criteria, consent interview, randomisation

Oversight expectations of the PI



FDA

Guidance for Industry

Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects

Additional copies are available from:
Office of Training and Communication
Division of Drug Information, HFD-240
Center for Drug Evaluation and Research
Food and Drug Administration
(Tel) 301-827-4573
http://www.fda.gov/cder/guidance/index.htm
or
Office of Communication, Training and Manufacturers Assistance, HFM-40
Center for Biologics Evaluation and Research
Food and Drug Administration
http://www.fda.gov/cber/guidelines.htm.
(Tel) 800-835-4709 or 301-827-1800
or
Office of Health and Industry Programs
Division of Small Manufacturers, International, and Consumer Assistance, HFZ-220
Center for Devices and Radiological Health
Food and Drug Administration
Tel: 1-800-638-2041
www.fda.gov/cdrh

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

Does the PI have "oversight" of the trial, and if so "how"

New ICH GCP guideline outlines the Principal Investigator (PI) oversight. The Principal Investigator roles are more clearly defined re responsibilities for trials (ICH E6)

NMA communication re teletrials policy

Future notification of the NMA policy for teletrials

- **Jurisdiction websites**
- **Online bulletins**

Questions