

*11<sup>th</sup> GHTF CONFERENCE  
WASHINGTON DC  
OCTOBER 2007*

*SG5: CLINICAL EVALUATION  
STATUS REPORT  
SUSANNE LUDGATE*

*Name MHRA  
Date 2007*



# ROLE

*to work towards convergence of clinical evidence requirements to yield common data for the purpose of acceptance by global regulators*

- harmonised definitions*
- harmonised guidance*
- MOU ISO TC 194*



# MEMBERSHIP

- Commission, COCIR, EDMA, EUCOMED*
- FDA, AdvaMed, NEMA*
- Health Canada, MEDEC*
- TGA, MIAA*
- MHLW, JFMDA*



# DOCUMENT FINALISED



## *clinical evidence: key definitions and concepts (N1R8)*

- clinical investigation*
- clinical data*
- clinical evaluation*
- clinical evidence*
- process data generation, clinical evaluation*



# DOCUMENT FINALISED



## *clinical evaluation (N2/R8)*

- when, why, process*
- general principles (scope, how performed, who performs)*
- sources of data (experience, literature, investigation)*
- appraisal*
- analysis*
- clinical evaluation report*



# IMPLEMENTATION PLANS



- Japan: intending to implement*
- EU: already implemented*
- Australia: progress in implementation*
- Canada: intentions incorporated in Regulations*
- USA: law and definitions compatible*



# DOCUMENT IN PROGRESS



## *IVD Subgroup (SG1)*

*Chair: Nancy Shadeed*

*“.....responsible for working on a harmonised format for pre-market submissions.....”*



# DOCUMENT IN PROGRESS



## *clinical investigation*

- when undertaken/ general principles*
- general principles need*
- general principles design*
- specific details design*
- ethical considerations*

# DOCUMENT IN PROGRESS



## *post-market clinical follow-up studies*

- what is it*
- when needed*
- type of study*
- plan, objectives*



# OBSTACLES



- ❑ *impact local law and regulations*
- ❑ *layers of review*
- ❑ *time to feedback*
- ❑ *lack mechanism to facilitate similar documents*



# THE FUTURE.....



*following completion of stated documents.....*

*No further plans!!*

