Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

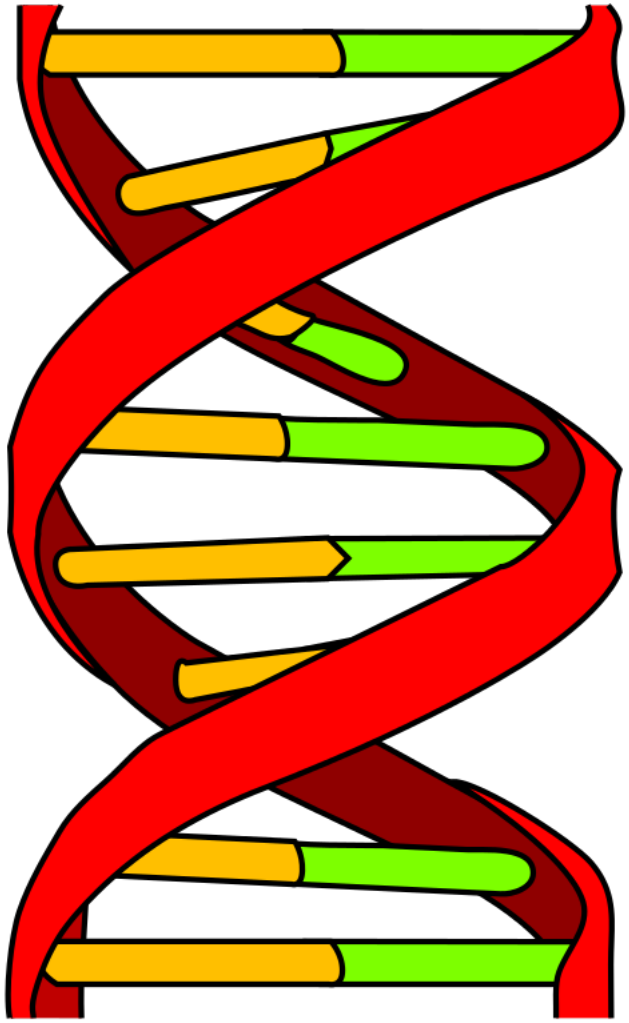
Genomics and Companion Diagnostics

Progress Report for Agency Board 12th February 2016

Genomics and Companion Diagnostics

Genomics – sequencing a human genome and comparing with a reference database of known sequences from previous patients to predict clinical outcome

Companion Diagnostics – using the result from a diagnostic test (perhaps a genomic test) to direct patient treatment



Key Deliverables for MHRA

- Genomics - Quality and Standardisation
- Genomics - Patient and Public Engagement
- Genomics - Software regulation
- Companion Diagnostics (inc EAMS)

Genomics – quality and standardisation

NIBSC has developed a programme for the development of standards for genomic diagnostics and cancer.

NIBSC has established a core facility for Next Generation Sequencing and bioinformatics

As part of the NIBSC stakeholder outreach programme, they will hold a workshop in February

Genomics - Patient/Public Engagement

MHRA are developing a work programme for involving patients and the public in our approach to genomics.

Two key issues of public concern:

- Security of personal data – identification of individuals from their data

- Use of personal data – “ownership” and future use of data for a purpose other than that for which consent was originally intended

Genomics - Patient/Public Engagement

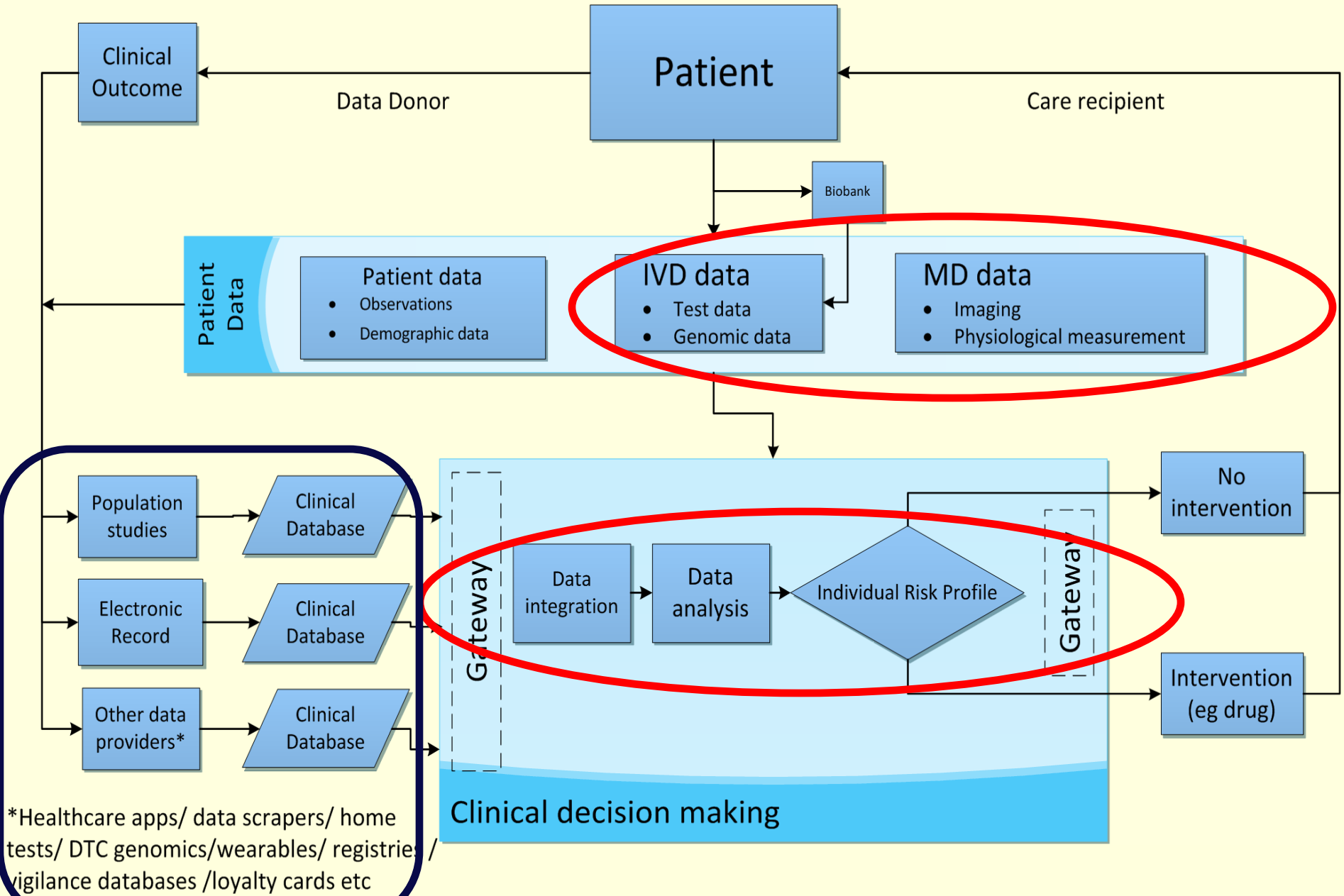
Next actions:

- Approach other key stakeholders with offer of collaboration on public dialogue to engage on the issues and thereby better understand levels of public awareness, concerns and viewpoints.
- Explore partnership with an organisation which could facilitate such an exercise in public dialogue.
- Identify costs and develop a business case to secure funding.

Genomics – software regulation

Software intended for analysing or processing data for a medical purpose may be covered by the regulations

'Healthcare is Data'



Genomics – software regulation

security

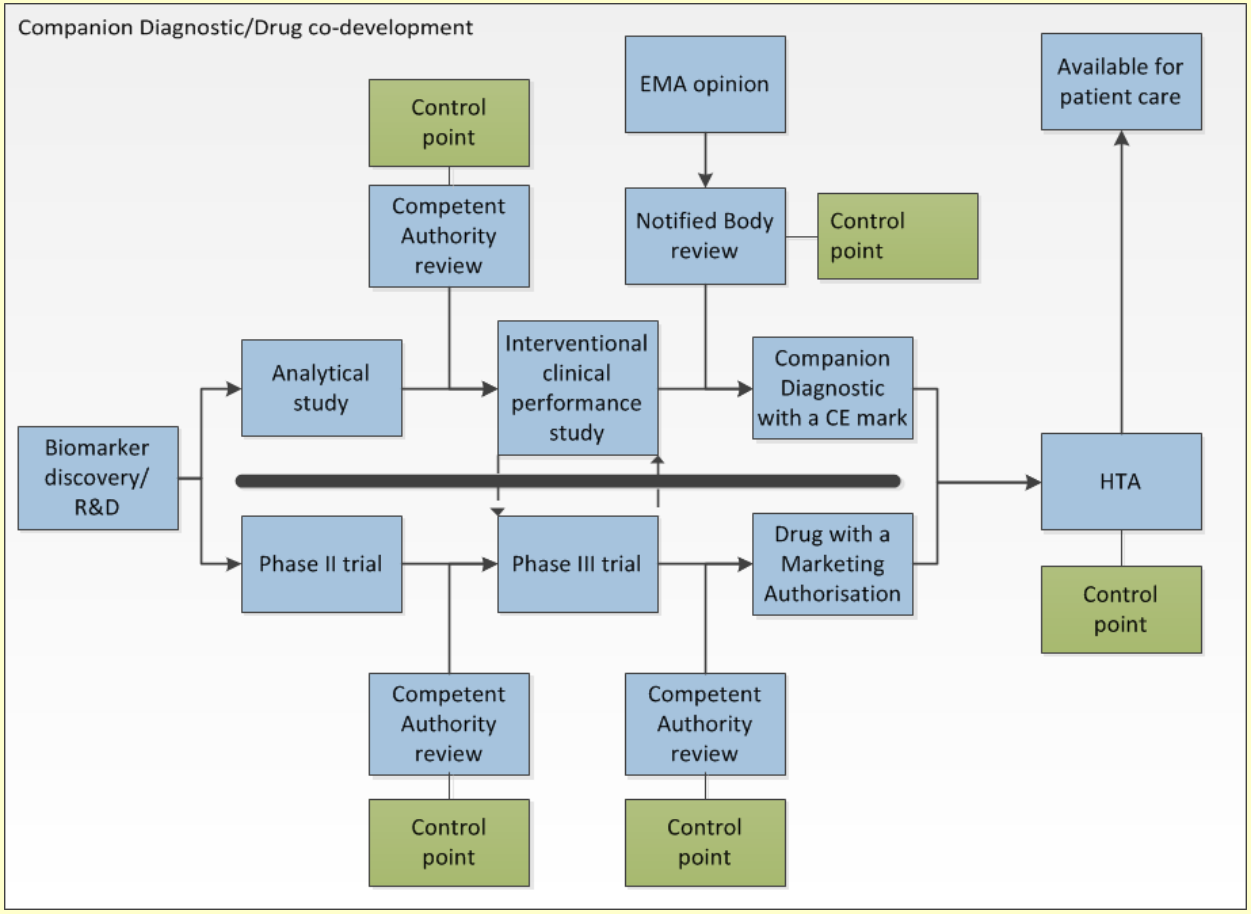
ethics

quality

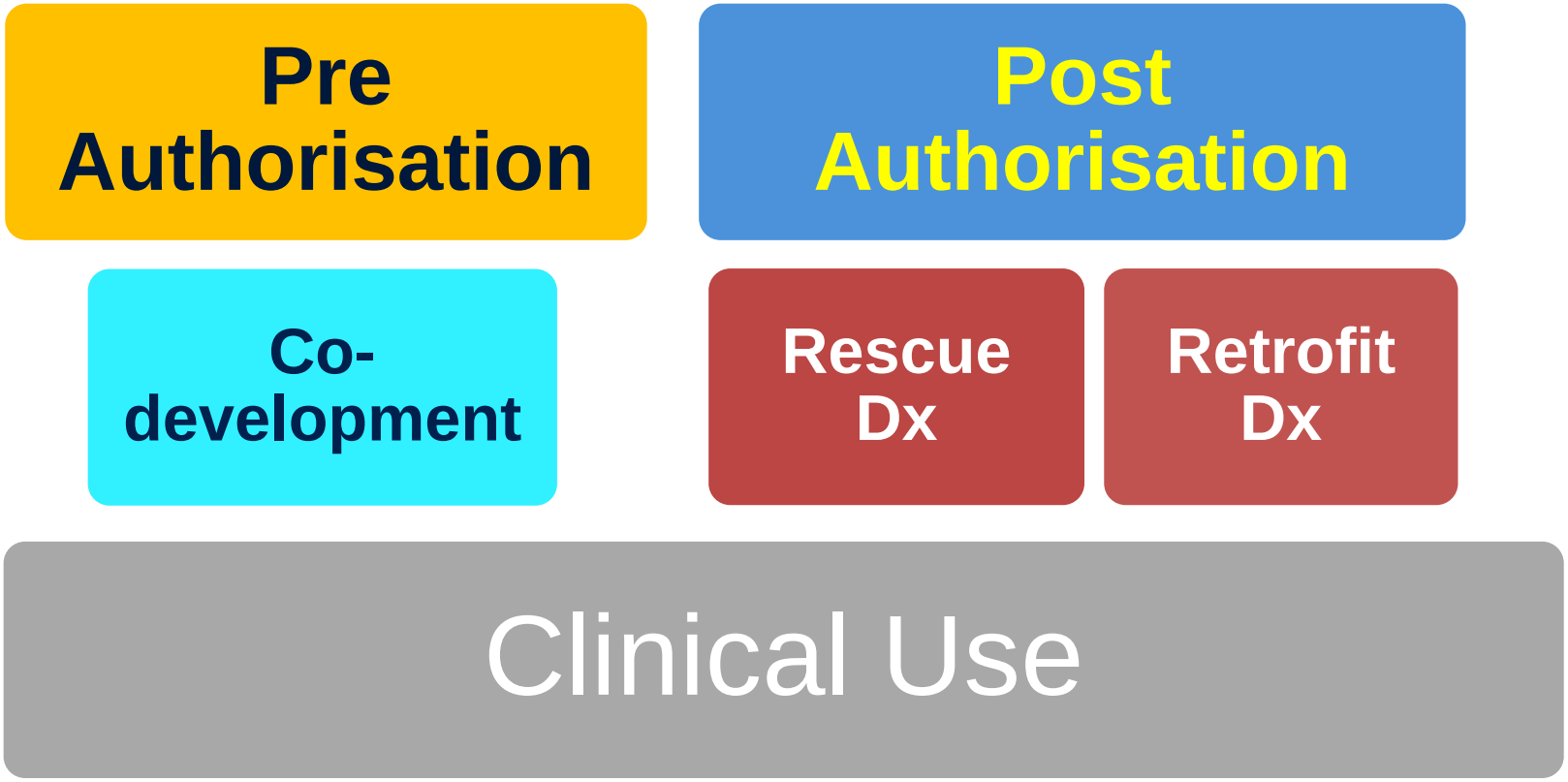
Companion Diagnostics – proposed definition

An in vitro diagnostic medical device which is essential for the safe and effective use of a corresponding medicinal product.

Potential regulatory pathway for companion diagnostics



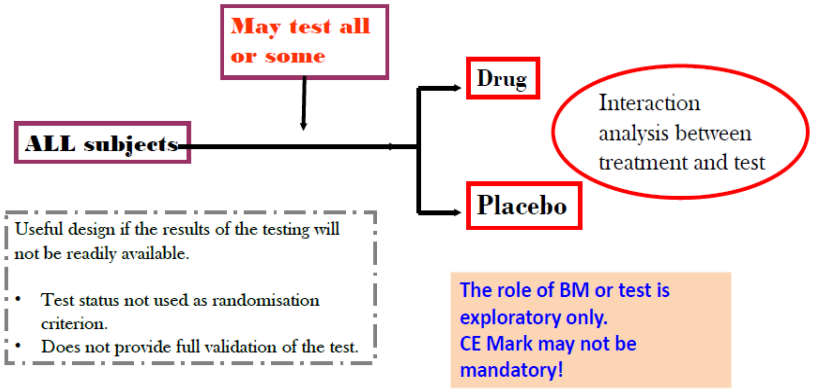
Facets of Dx/ CDx development



Evidence generation & requirements will differ!

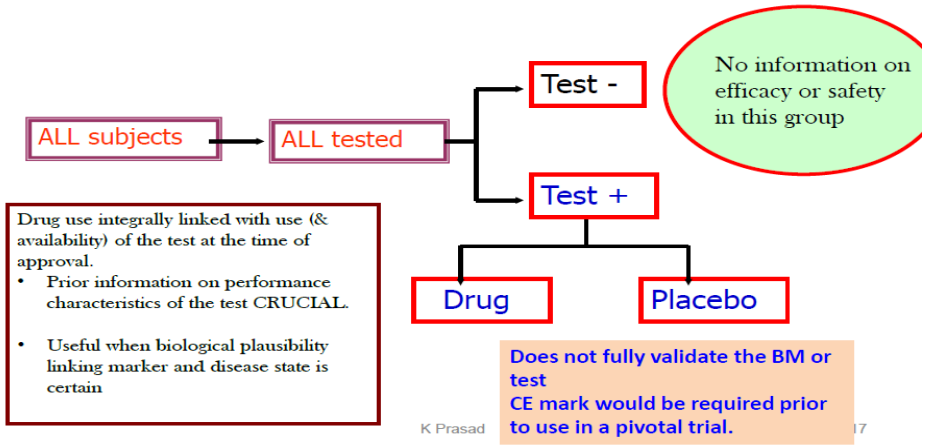
Clinical trial designs and Guidance

Clinical Study Designs (1)

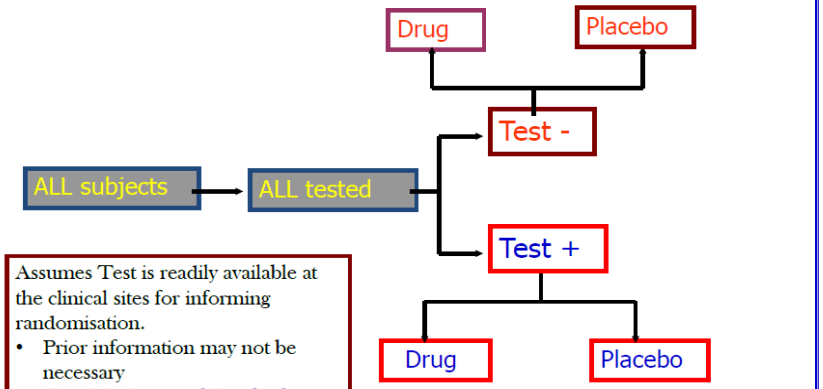


Clinical Trial Designs (2)

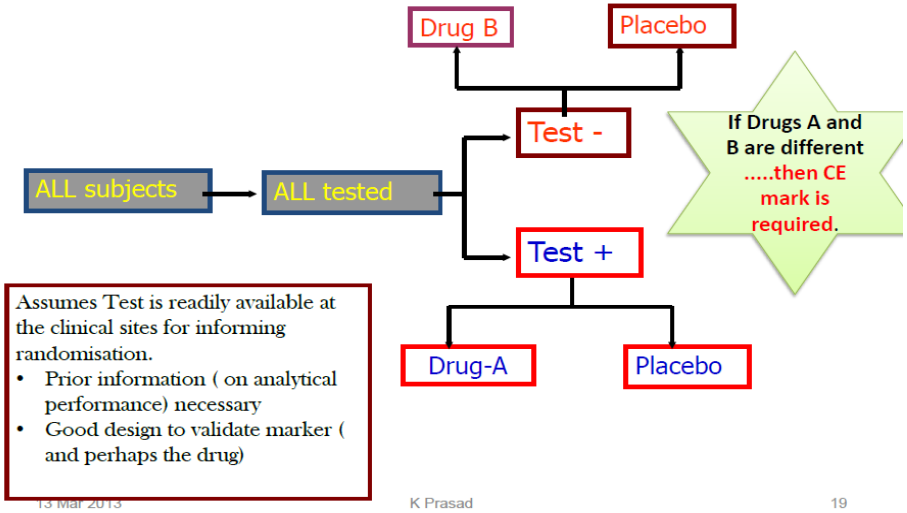
Enriched or targeted design



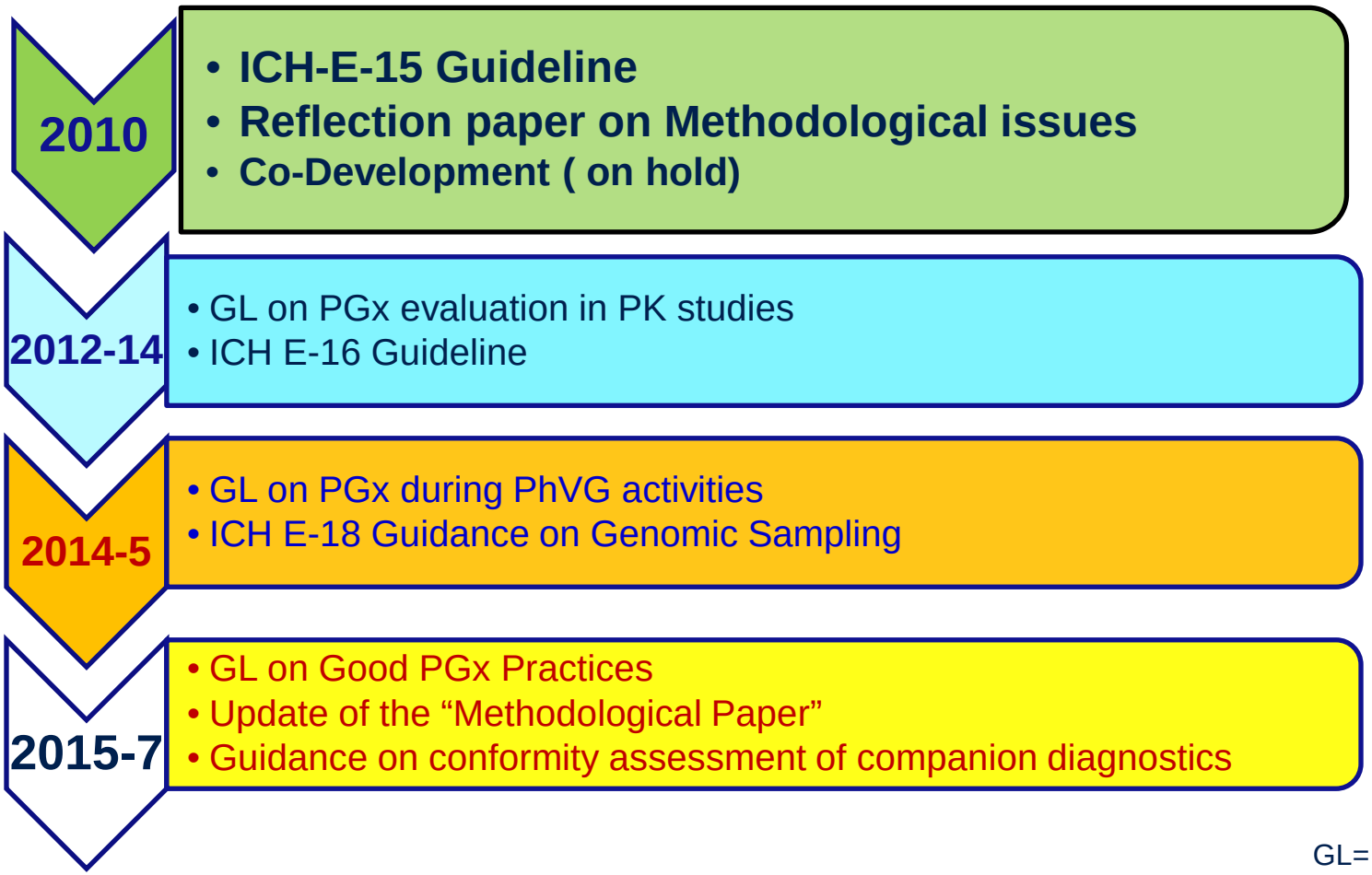
Clinical Trial Designs (3)



Clinical Trial Designs (4)



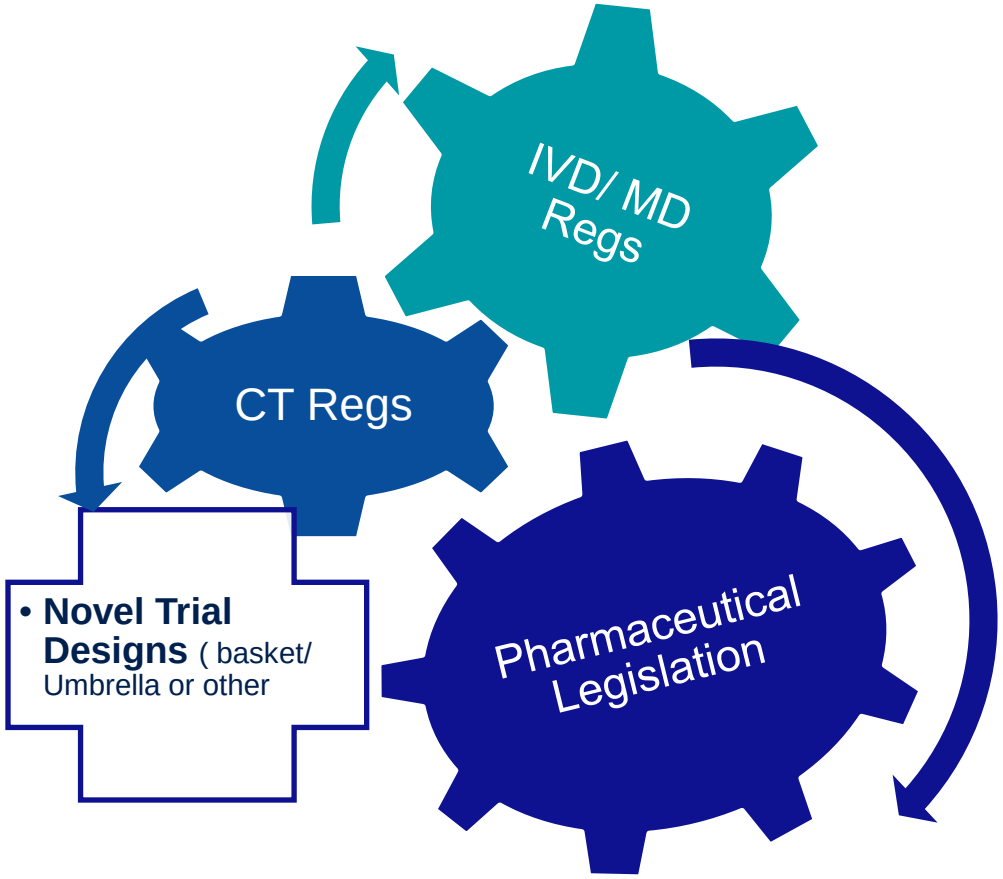
Existing/ Upcoming EU or ICH Guidelines in this area



GL= Guidelines

PGx= Pharmacogenomics

Coordination/ Streamlining



Areas of Interest / Focus

- Clinical Trials for IVDs/ MD
- DX- Research Use/ CE mark/ other before use in clinical trials
- Impact of (and on) novel trial designs

Key messages

- *MHRA has an interest in clinical data*
- *MHRA will seek to engage with wide range of key players*
- *MHRA will seek to act as facilitators to promote innovation*