Can we ease the ethical review of Clinical Trials in the EU? (within current/ future law)

A non-legislative proposal to develop accreditation & mutual recognition between EU Member State RECs

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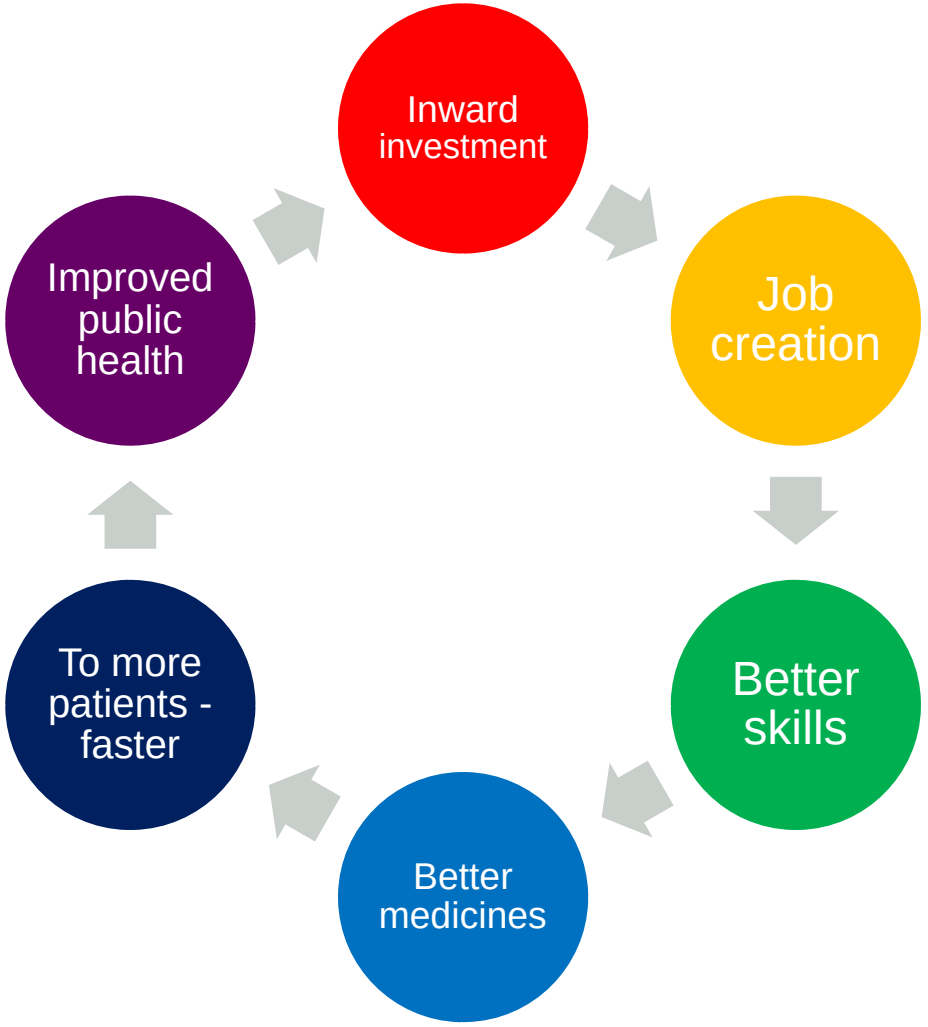
Outline

- Background
- Principles governing our work
- Who is involved?
- What do we propose?
- How can we get there?
- Questions for the Panel

Clinical research is important



Clinical research

- Clinical research is important but the number of clinical trials is declining in the EU
  - Recession
  - Globalisation
  - Complex environment: 27 member states (MS), Clinical Trials Directive, diverse MS requirements.

- Change: new draft Clinical Trial Regulation being discussed
  - RECs and Competent Authorities (CA) not mentioned but ‘Member States’ (EU-RECs and Competent Authorities) must comply with regulation timelines

Ethics committees: a crucial function yet -

- Different approaches in each MS
- Limited EU level coordination*
- Overworked & under resourced

So could the burden be reduced?

Four important principles for this work

1. We believe the role of RECs in the approval process is crucial, this role must be retained and RECs supported.
2. REC decisions are taken at Member State level and we do not question this.
3. We want to be inclusive and involve as many “stakeholders” as possible.
4. We will ensure our proposal is complementary to the revised clinical trials regulation.

A question

Is there really anything fundamental to suggest we could not accept the decision from another REC?

Janet Wisely – CEO Health Research Agency – December 2011
(includes National Research Ethics Service)

The proposal & our aim

Optional accreditation and mutual recognition approach within the framework of existing legislation (but also looking to the future).

Why accreditation & mutual recognition of EU-RECs?

- CA have set up worksharing procedures within existing legislation (the Voluntary Harmonisation Procedure).
- Could we do something similar for EU-RECs? Recognition would be on the basis of assurance of the system itself against agreed standards.
- Details need elaboration and agreement.

Who are we seeking to involve?

- Clinicians/ academics, regulators, RECs and industry. Contributors to date:
  - European Forum for Good Clinical Practice
  - EU-REC representatives from France, Germany, Netherlands, Spain and the UK
  - Industry trade associations: ABPI, BIA, EFPIA, Farmaindustria, LEEM
  - The UK competent authority (MHRA)
  - Academic researchers (UK Academy of Medical Sciences)

(We welcome more!)

Accreditation & mutual recognition (1)

- Need a forum for RECs to meet and exchange best practice (EFGCP and EUREC). Longer term, strengthening EU REC networking may need Framework funding/ legislation?*

- Establish shared principles in the generation of a REC approval. This could start with just 2 or 3 EU MS RECs.

- Establish recognised quality assurance/ accreditation** to recognise that different MS quality controls are equivalent - even where processes are non-identical.

Accreditation & mutual recognition (2)

- Establish ‘light touch’ Member State (MS) REC approval when there is mutual recognition of the REC assessment process in another MS.
  - E.g. simplifications like subcommittee review, reduction of elements assessed etc.

- The ‘light touch’ approval process should not duplicate the REC assessment process but focus on documentation needed for the conduct of that study in that MS.

- A MS REC may need to review all application elements by local law, but these comments could be fed back to the reviewing REC for coordination.

Our proposal and the draft CT regulation: issues to consider

- Could the EU Portal facilitate the set up and use of accreditation and mutual recognition by EU-RECs?

- Could this process help EU-RECs better meet timelines in the new regulation?

How do we get there?

- Raising awareness and engaging cross sector.
- Proving concept with a small pilot - 2 to 3 MS RECs and Competent Authority/ sponsor support.
- Additional EU MS RECs can join scheme if the concept is proved.

Questions for the Panel

1. What would (your) MS(s) accept as satisfactory criteria for recognising RECs opinions in other MS?
2. What would your RECs wish to receive from the original REC?
3. How could we facilitate communication between RECs?
4. How might you see your RECs respond to a CTIMP approved elsewhere”?
5. Could this approach be used in the 3 clinical trial classifications in the draft regulation (low interventional to advanced therapies?