Technology & Policy; uneasy bedfellows?

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Technology & Policy – uneasy bedfellows?

**Technology**
- New treatments: Synbio, Stem cells, Nano-meds
- Delivery systems: Time specific, Site specific, Physiologic
- Production: Synbio
- New trial technology: E-trials, Adaptive trials
- Monitor treatment outcome: E-Health Record
- "Hovering": life style adherence
- Patient stratification: Genomics
- Predictive models: based on database

**Policy**
- Synbio: “call for moratorium”
- Stem cell issues
- Divergent evidence standards: drugs vs. devices
- Research “ethics” Good Clin. Practice standards
- Data protection laws
- Privacy issues

**Prod. & pre-clinical**
- Clinical development
- Health care environment

- Commercial confidentiality of data
- Fear of misuse of genetic data
Aligning technology and policy…

Overarching principles:

• Emphasise benefit-risk, not risk (and steer clear of the precautionary principle)
• Bring the patients’ voice on board (and mind the gap between patients and consumer advocates)
• Open the black box (full transparency: clinical trial data, decision making process, CoI, …)
• Make policies, regulations adaptive; (e.g. sunset clauses for evidence standards?)
Thank you!

(EMA, Canary Wharf, London)