



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Technology & Policy; uneasy bedfellows?

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Technology & Policy – uneasy bedfellows?



EUROPEAN MEDICINES AGENCY

Technology

New treatments:
Synbio
Stem cells
Nano-meds

Delivery systems:
Time specific
Site specific
Physiologic

New trial technology:
E-trials
Adaptive trials

Monitor treatment outcome:
E-Health Record

“Hovering”:
life style adherence

Production: Synbio

Patient stratification: Genomics

Predictive models: based on database

Prod. & pre-clinical

Clinical development

Health care environment

Policy

Synbio: “call for moratorium”

Commercial confidentiality of data

Fear of misuse of genetic data

Stem cell issues

Divergent evidence standards:
drugs vs. devices

Research “ethics”
Good Clin. Practice standards

Data protection laws

Privacy issues



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, Col, ...)
- Make policies, regulations adaptive; (e.g. sunset clauses for evidence standards?)

Thank you!

(EMA, Canary Wharf, London)

