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What do I expect from the EMA in the next five years?

Sir Mark Walport, Government Chief Scientific Adviser

18 March 2015

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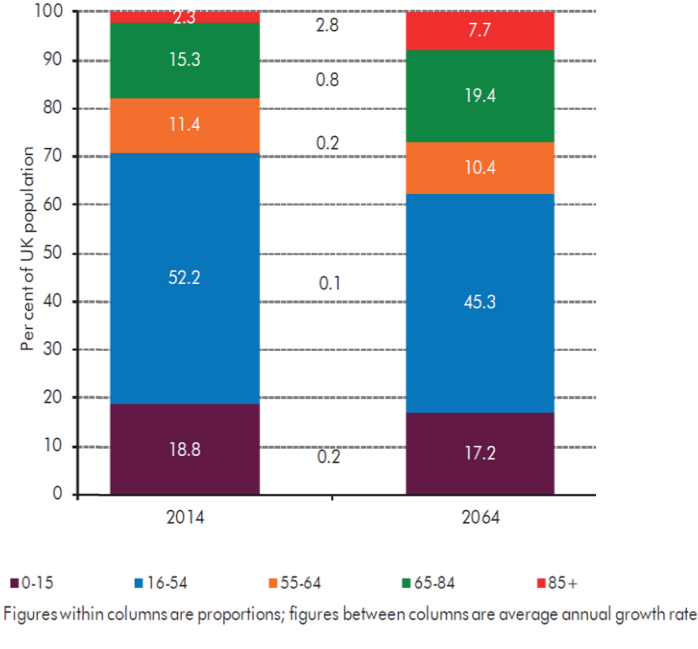
The changing context for regulation

Form should follow function.

Big picture:

- Integrated care
- Big Data, genomics, proteomics, metabolomics
- Demographic change
- Internet of Things, 2nd Digital Revolution
- Affordability
- Healthcare as an economic asset



1961 is England and Wales only. Figures within columns are proportions; figures between columns are average annual growth rate
Source: ONS

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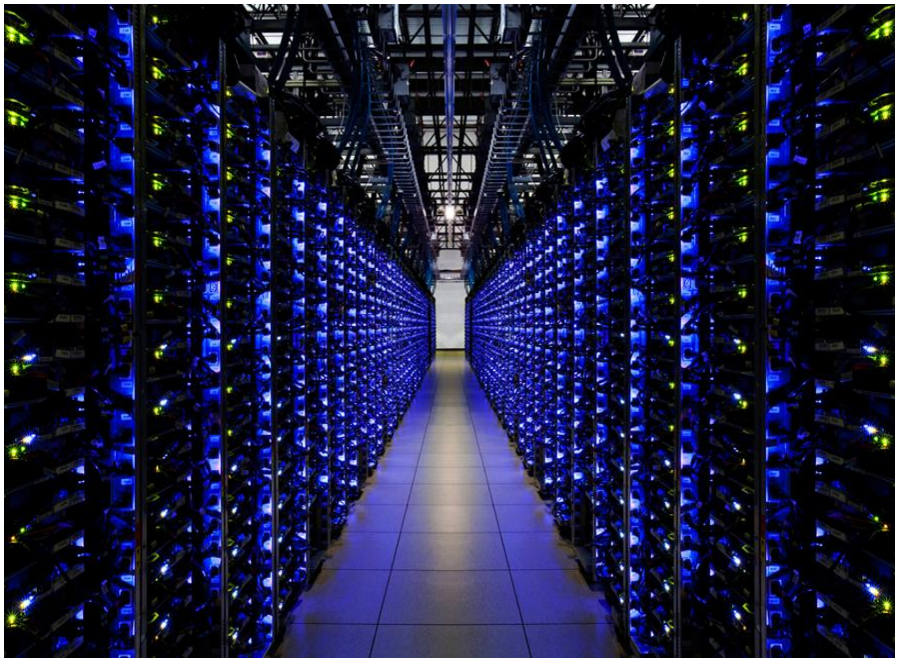
Smarter, more complex medicine

- Digital health:
  - Better practice
  - More effective
  - More efficient
  - More accountable
  - More detailed monitoring



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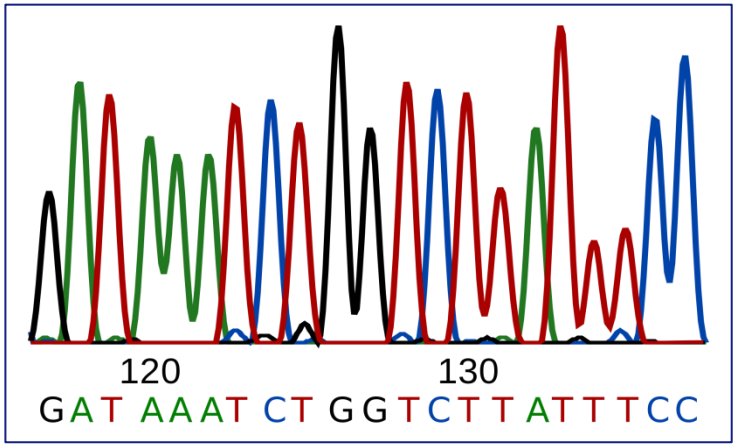
Smarter, more complex medicine

- Precision and personalisation:
  - Genomics-led
  - More targeted, adaptable
  - Effect and side effect better understood
  - Better monitoring
  - Greater dose flexibility
- Combination therapies
- Measured compliance



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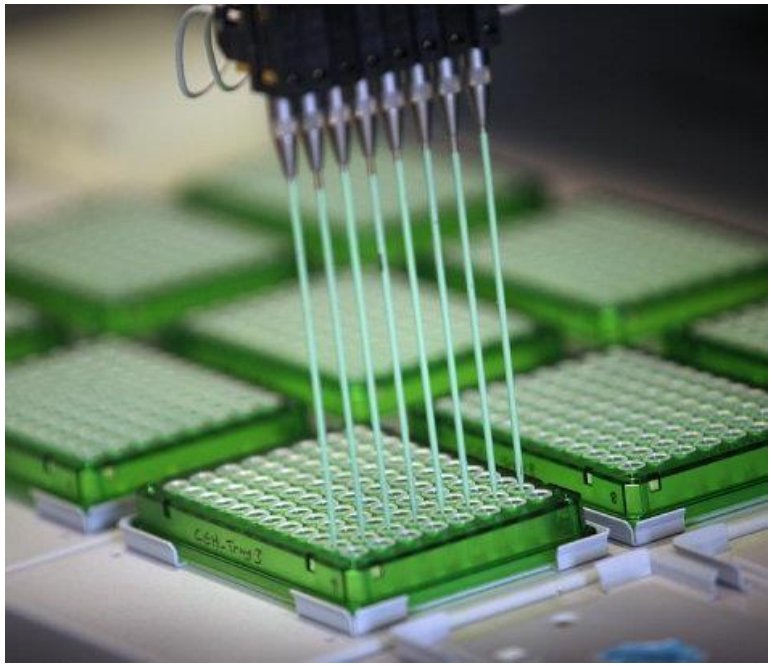
Need for more sophistication

- Regulation will have a more important role throughout the lifetime of a medicine
- Needs to be smarter in five ways:

1. Pace, efficiency and effectiveness
2. Precision and personalisation
3. Complexity
4. Lifetime analysis
5. Affordability of process



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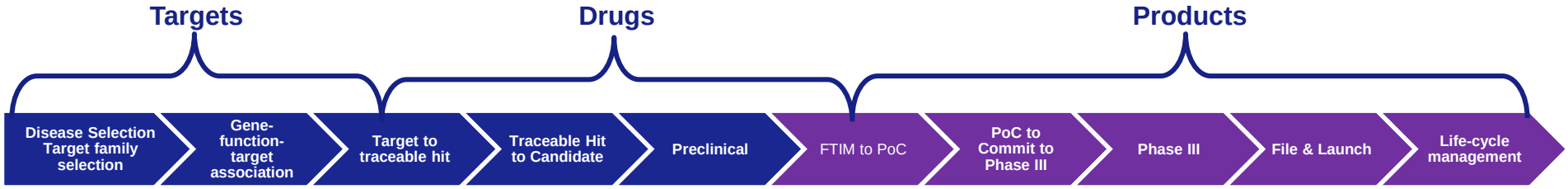
Regulating at an appropriate pace

- Regulation often seen as a drag on innovation: ‘prove it’s safe’
- Pace of response to diseases should be needs-led
- Regulatory process needs to match that pace
- Trust in regulators would be undermined by being a cheerleader
- But being trustworthy means delivering new treatments we need, at a cost we can afford



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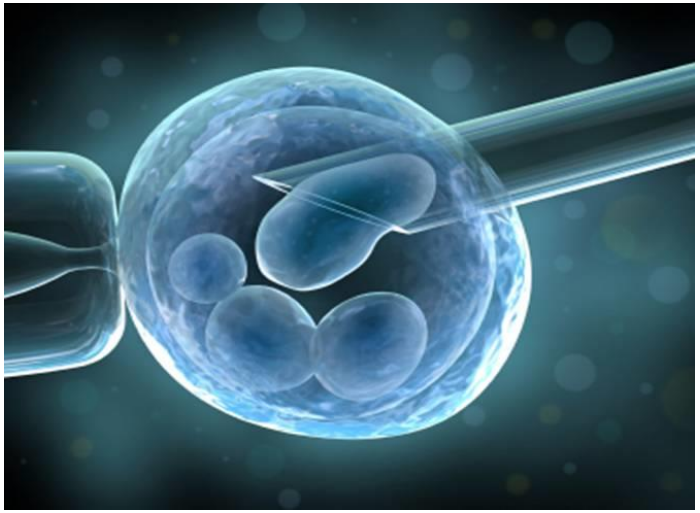
Generic challenges to regulators

- Economic regulation – a systems approach
- Asymmetric incentives
- Encrusted regulation
- Regulation when science meets values



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Case Study: Vaccines

- Ebola: No vaccine ready, placebo trials at 70% fatality?
- Flu: old technology for a fast evolving virus
- Inherent complexity:
  - A cassette approach
    - Adjuvant
    - Antigens
    - Carrier

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Regulation as a driver of innovation

- Incentivise balance between innovation and precaution: better accountability
- Novel approaches to accelerate adoption of new innovations
- Incentivise therapies for neglected diseases and neglected groups
- Regulation to promote and mandate new and better approaches, or just in response to them?

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Regulating precision and personalisation

No longer a question of is it a good drug, but right drugs, right combination, for the right person…

- How can regulation support a personalised approach?
- Role of technology in guaranteeing provenance, dealing with counterfeits
- Integration with digital care systems
- And at the right time, right dose…

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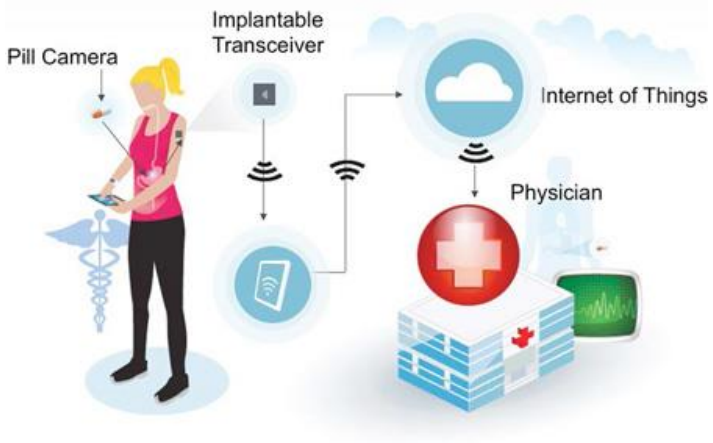
Regulating post-prescription

Technology exists to monitor dosing behaviour…

- Could revolutionise correct application of drugs
- Provide greater accountability
- And dramatically improve understanding of effects and side effects
- Role of regulation to drive this?



myHealth
The Patient Portal
beta

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Implications for trials and regulation

Imagine we have data on all clinical drug use, and its efficacy…

- Blurs the lines between clinical trial phases, and application
- Continual analysis of effects
- Need for conditional approval, adaptive licences?

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Affordability

- No sense austerity is over
- Efficiency imperative is as true for regulators as the NHS

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Not all a regulators job

- Industry has a responsibility to work with health system to produce the medicines we need
- And that requires health community giving a clearer description of its needs
- Role of regulators as a convenor for that conversation?

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So in 5 years we need you to be…

- Driving innovation through regulation
- Ensuring a personalised approach is increasingly the norm
- Handle complexity
- Matching the pace demanded by clinical need
- Enabling the use of digital technologies to ensure provenance, proper dosage and measuring responses to therapy