DIGITAL HEALTH AND CARE ALLIANCE

DHACA's mobile apps process

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Warning

- The presenter is not a qualified lawyer or clinician; please check any statement you read or heard during this presentation with an appropriate professional before relying on it.

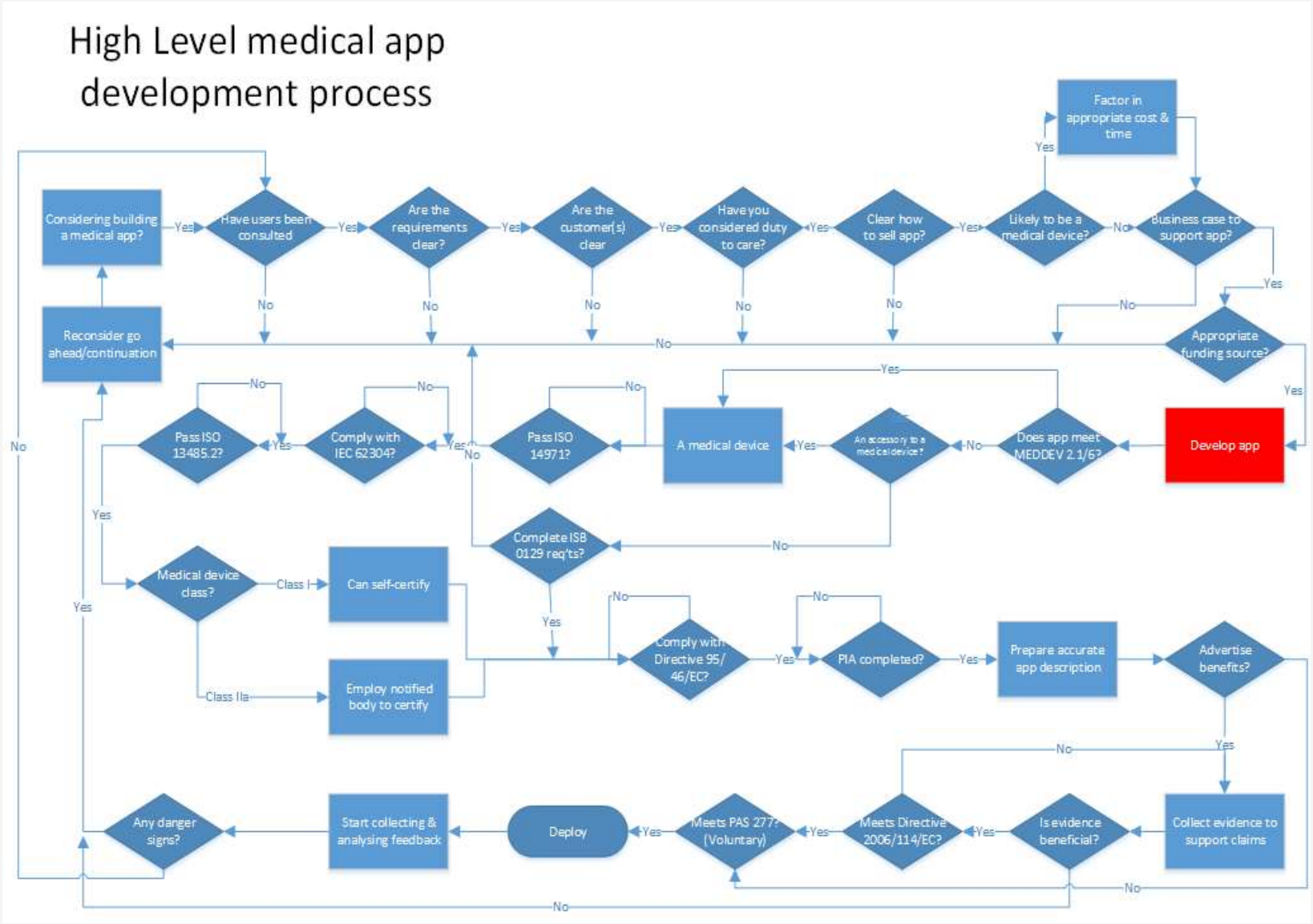
Process

- Final document at www.DHACA.org.uk, then navigate to SIGs, mHealth apps

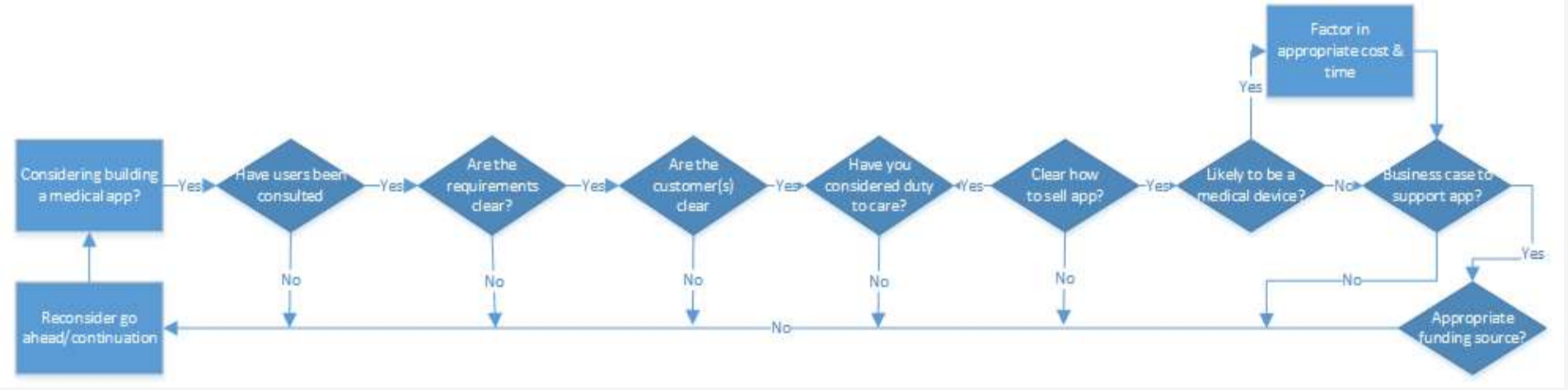
New Yorker, Daily Cartoon 15/9/15

"Your previous provider refused to share your electronic medical records, but not to worry—I was able to obtain all of your information online."

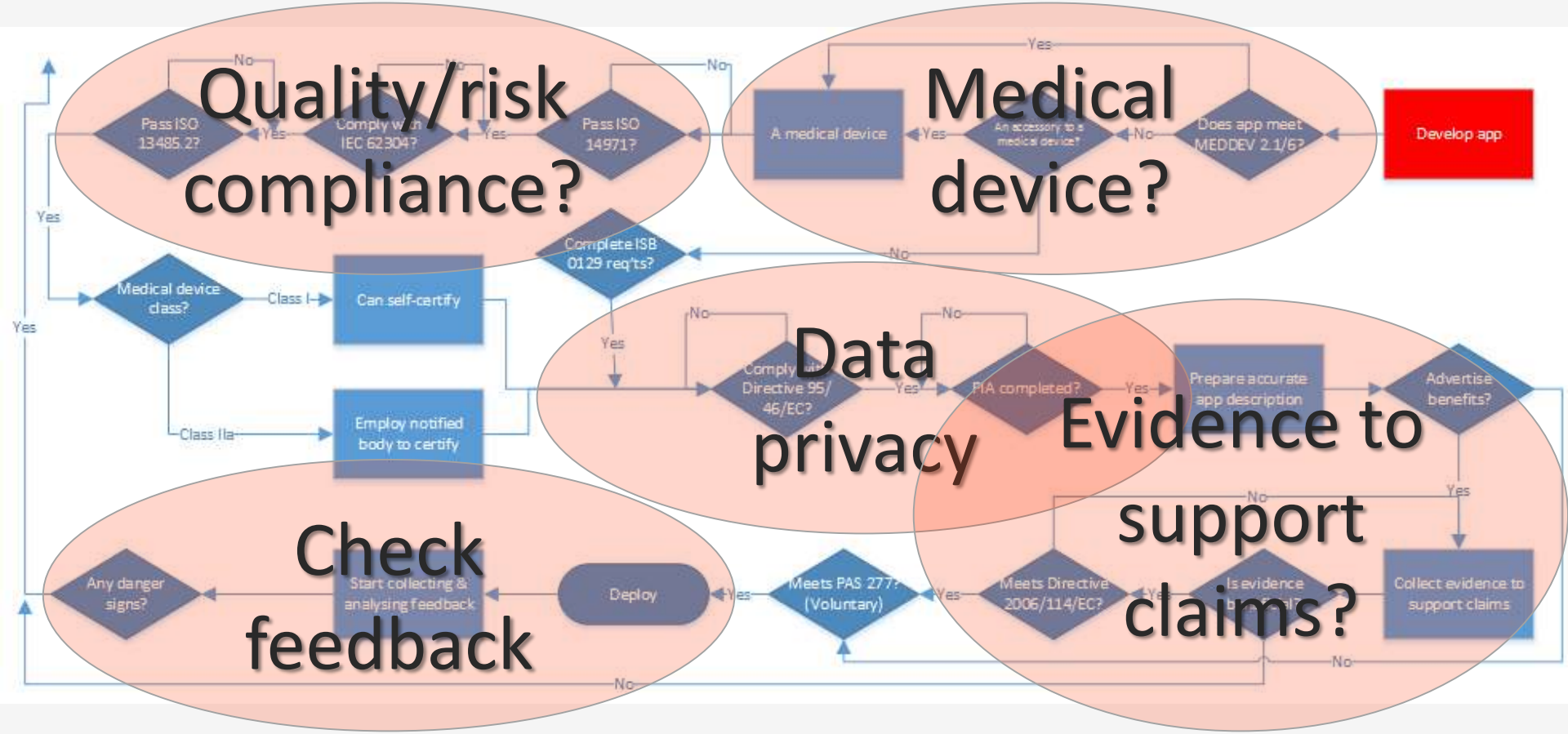
Developing an app is non-trivial



The ‘top row’ does not involve regulation



…the other rows do!



Medical device legislation

- Medical Devices Directive (93/42/EC) includes software and applies to
  - …diagnosis, prevention, monitoring, treatment or alleviation of disease…(and other activities)
  - Apps are active medical devices if they meet medical device definition
  - Prescriptive advice on Class
  - Key concept is *intended use*
- Detailed definition of what constitutes a medical device in Meddev 2.1/6

Quality & risk

- ISO 14971: a standard for the application of risk management to medical devices
  - Establishes the requirements for risk management, needed eg ISO 13485.2
- ISO 13485: a medical device-specific quality management standard
- IEC 62304: identifies three different safety classes that determine appropriate software cycle processes
- (Commissioner has obligations too)

Information privacy

- Directive 95/46/EC covering all aspects including need for appropriate encryption & security, expected shortly to be replaced by a regulation with stronger powers
- Important concepts of *data minimisation*, *data protection by design*, *data protection by default*
- Privacy Impact Assessments (PIAs) expected to become compulsory
- (Again commissioner has obligations too)
- Note that FDA recently banned use of an infusion pump as it was too easy to hack

Consumer protection

- Misleading & Comparative Advertising Directive 2006/114/EC
  - Benefits can only be advertised if evidenced
- Issue of how to evidence benefits in a fast-moving business is a continuing issue
  - Strong NICE engagement now
- (EC Code of practice on information protection for consumers)

Feedback

- Key safety measure, and opportunity to improve
- Apps offer relatively simple feedback on:
  - Continuing benefit
  - Issues
  - Opportunities

Conclusion

- Regulation is unavoidable
- Regulation is complex
- Even if you aren't building a medical device, you still need to be aware of data privacy and consumer protection legislation
- In six months it will begin to change, and continue to
- …and there's much more…

Thank you

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