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from diagnosis to cure

First simple question in Industry's Implementation

What do I have to do…

and by When?

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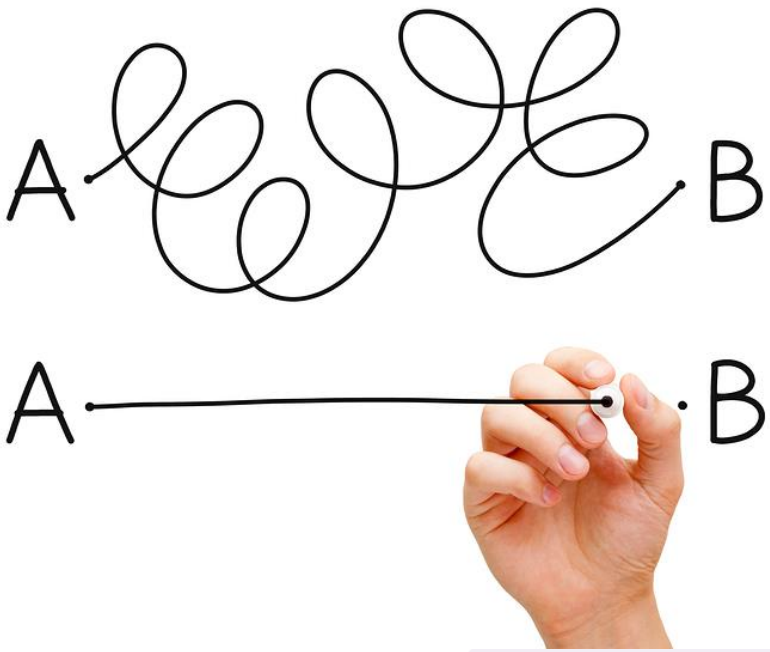
MDR 1/3 = IMPLEMENTATION TIMINGS

Clarity needed on timings so industry can efficiently move to the new rules:

- as quickly as possible and
- with minimum disruption for patients, health care professionals and health systems



Examples:

- Notified body designation
- Which Implementing Acts when?
- Certificates
- Databases and registrations

IMPLEMENTATION – Do the Math!

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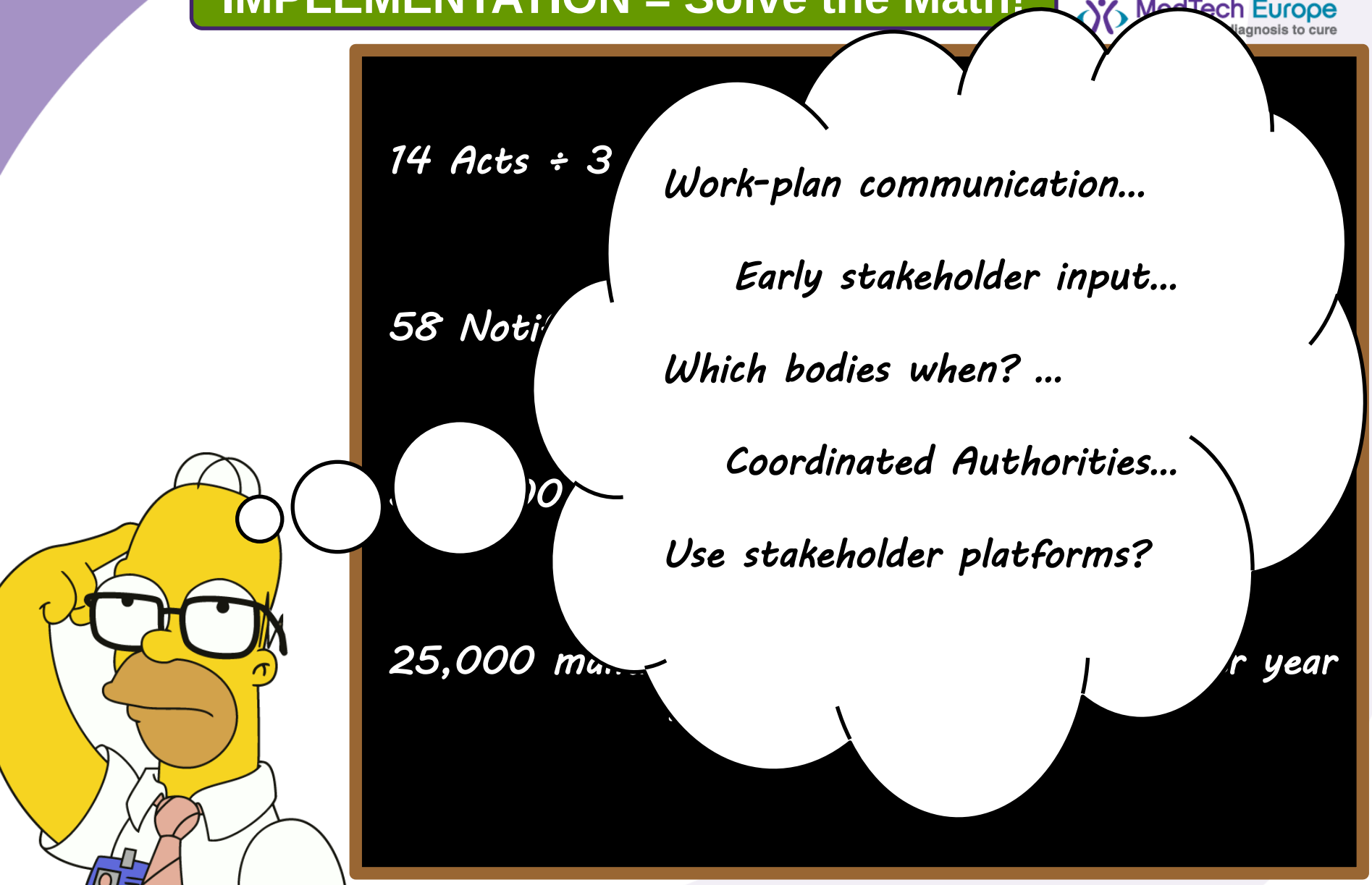
14 Acts ÷ 3 years = 4·7 per year
...or one every 2½ months

58 Notified Bodies ÷ 2½ years = 23 per year
...or one every 2 weeks

500,000 Devices ÷ 3 years = 166,667 per year
...or one every 3 seconds

25,000 manufacturers ÷ 3 years = 8,333 per year
...or one every hour

IMPLEMENTATION = Solve the Math!



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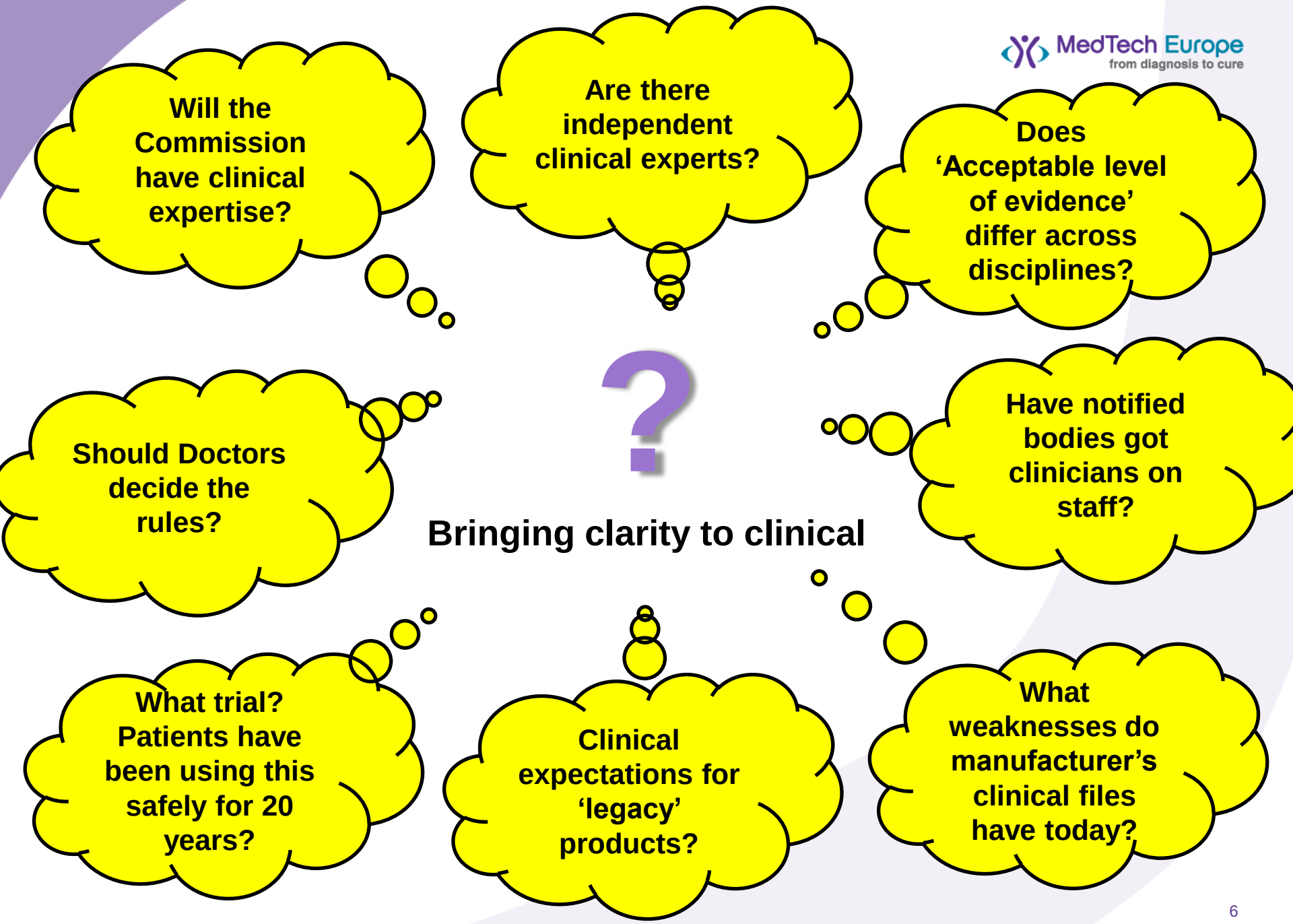
MDR 2/3 = CLINICAL EVALUATION

Need clarity for industry to effectively plan and comply in time:

- Insufficient detail on extent of data expected
- Incoherent definitions and terminology, overly complex text
- Inconsistent use of terminology
- How to practically demonstrate equivalence
- The practicalities of addressing post-market clinical follow-up and annual reporting requirements


Will the Commission have clinical expertise?
Are there independent clinical experts?
Does 'Acceptable level of evidence' differ across disciplines?
?
Should Doctors decide the rules?
Have notified bodies got clinicians on staff?
Bringing clarity to clinical
What trial? Patients have been using this safely for 20 years?
Clinical expectations for 'legacy' products?
What weaknesses do manufacturer's clinical files have today?

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And I haven't even begun to discuss…

…RESOURCES

All actors will need to adjust and apply resources:

- Manufacturers
- European Commission
- National Authorities
- Notified Bodies
- Standards Bodies
- Authorised Representatives
- Distributors
- Importers
- …

Reminder to self – MDR Resources