

Drug-Device Combinations : Supporting innovation and addressing regulatory challenges – Industry Perspective

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Digital Therapeutics : How to regulate the treatments of the future?

Digital Therapeutics : Definition

A Digital Therapeutic is defined as the use of a connected device, sensor or software which optimises the use of medicines through:

- Encouraging appropriate medication use
(e.g. adherence, digital device training)
- Maximising medical benefits
(e.g. self-management of AEs, virtual patient/HCP interactions)
- Allowing point of care data collection
(e.g. bio-sensors, environmental data, PROs, mobility, sleep)



THE CONNECTED PATIENT

A combination of digital and data-rich human interventions extending 'beyond medicine' to enhance the patient experience, improve clinical outcomes and optimise medical practice

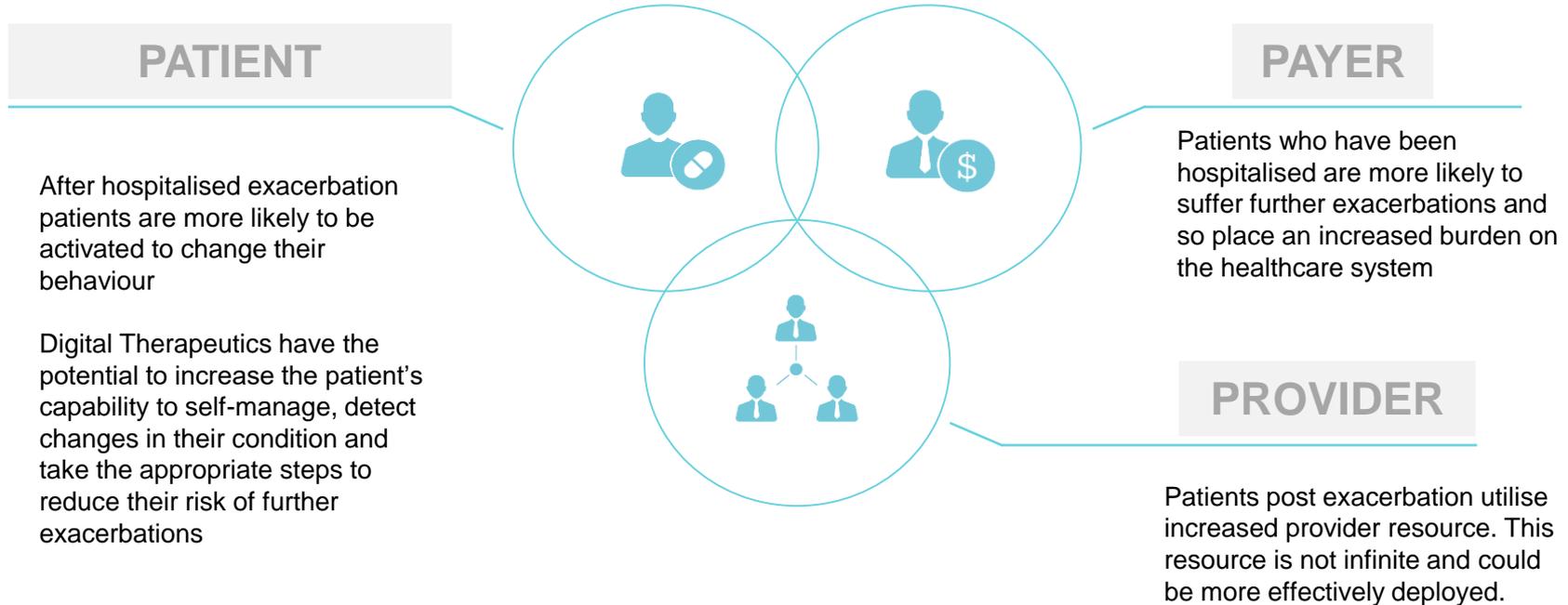


**MEDICATION
MANAGEMENT**

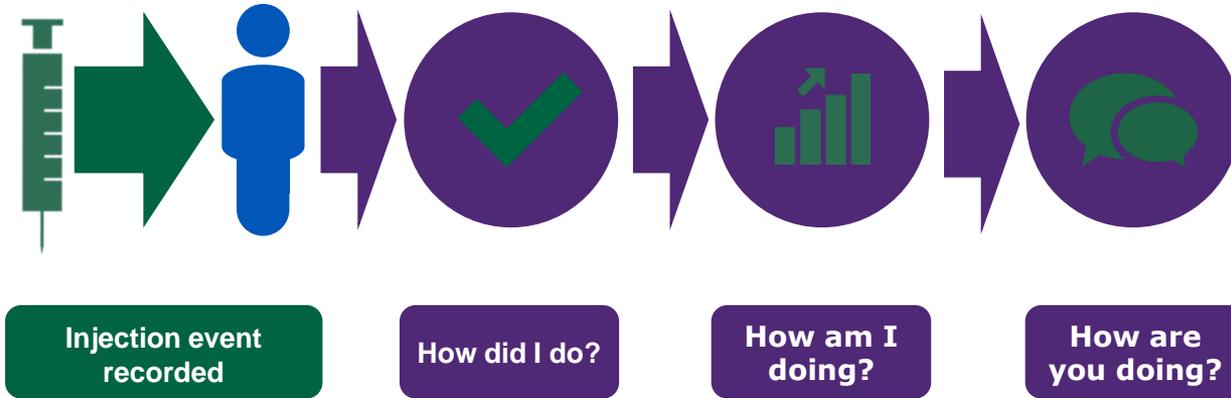
EVIDENCE

Digital Therapeutics must meet the needs of multiple stakeholders

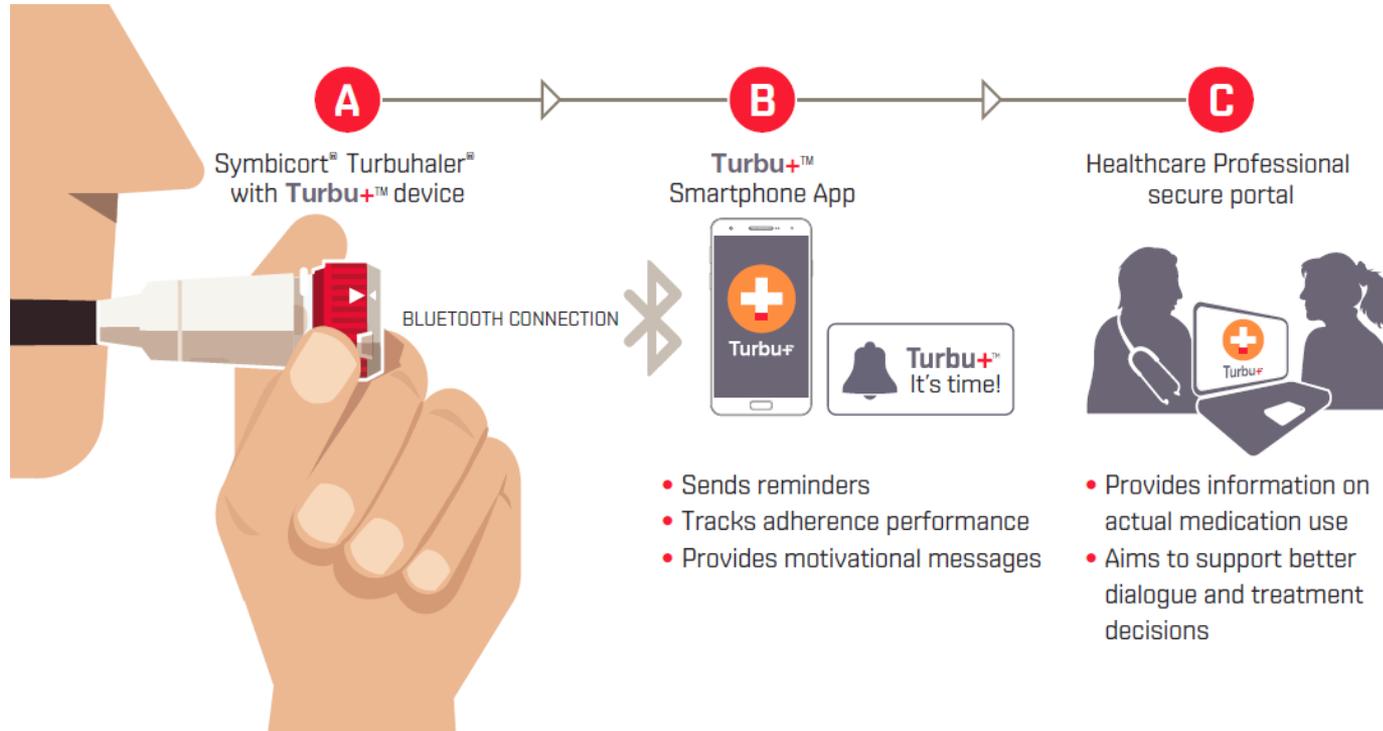
Illustrative example: Supporting COPD Patients on discharge from hospital



Digital Therapeutics : Building engagement

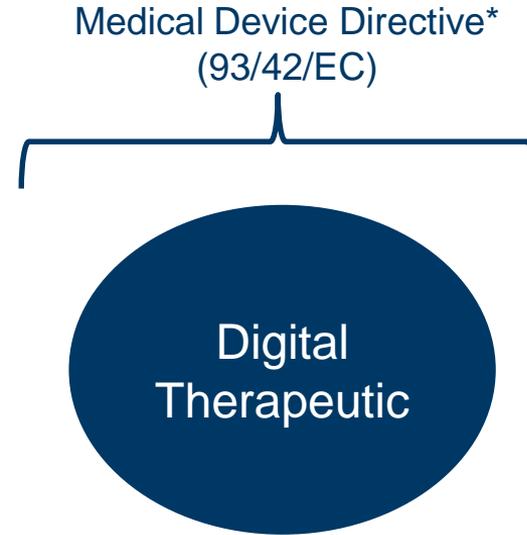
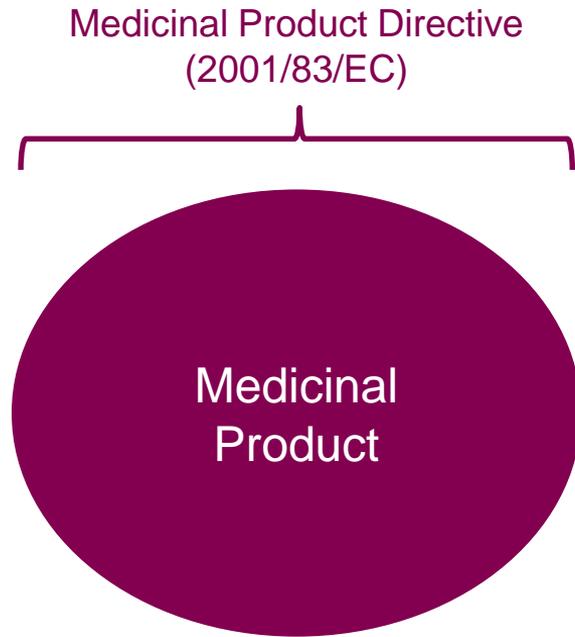


Case Study : Turbu+ reinforces Symbicort real life efficacy by supporting the right patient behaviour



Regulatory boundaries are shifting...

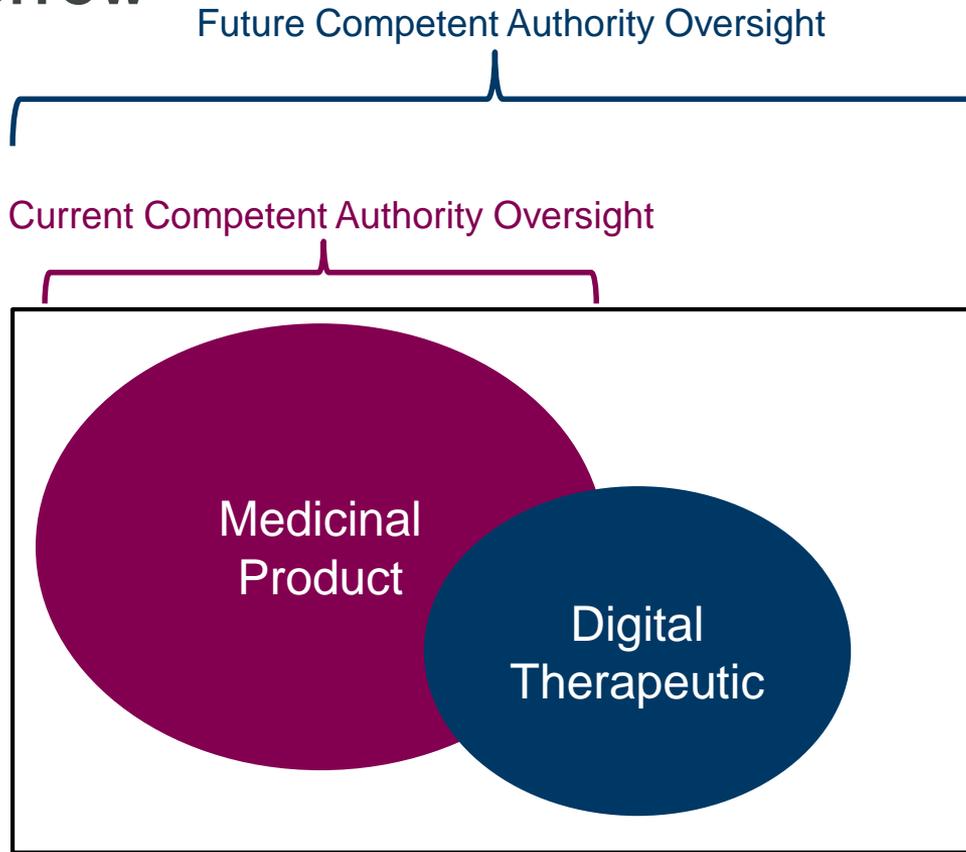
Today



* Will be replaced by Medical Device Regulation (2017/745)



Regulatory boundaries are shifting... Tomorrow



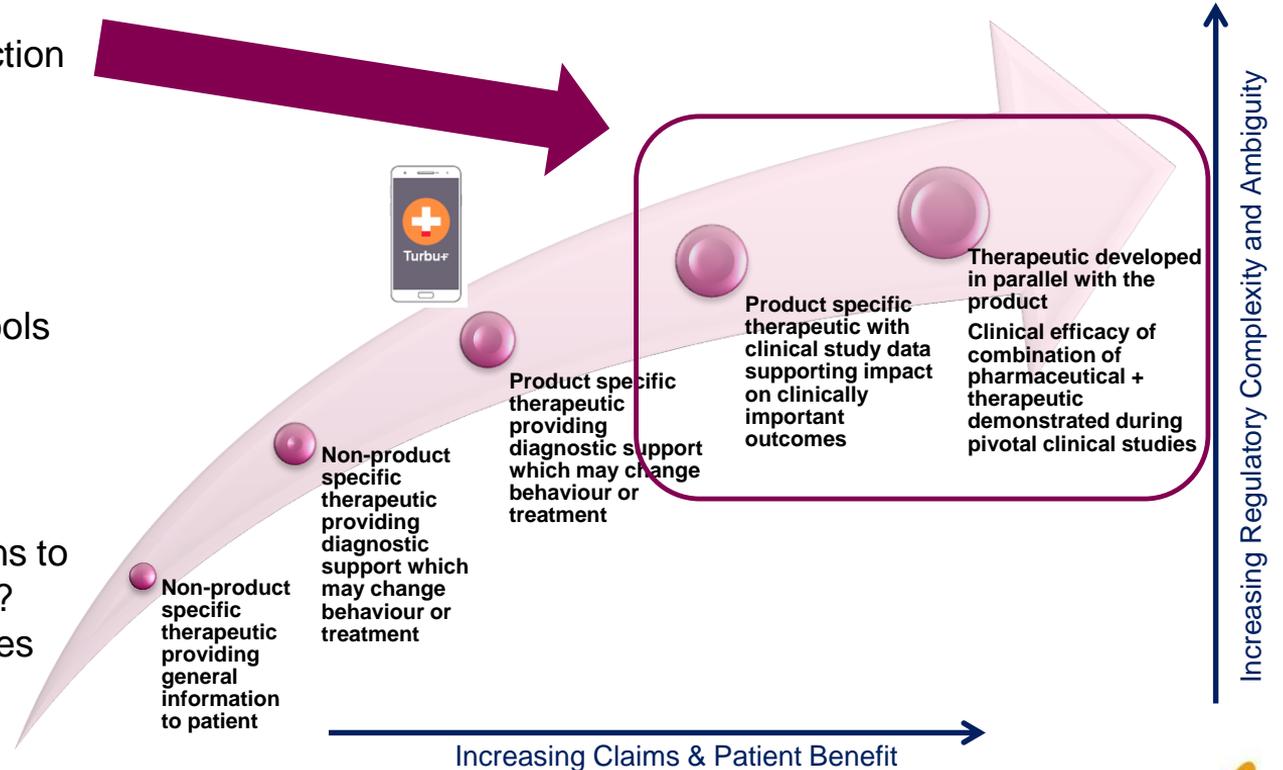
Challenge:
How to regulate a
Digital Therapeutic
as part of the overall
product?

Regulatory Oversight

Lack of regulatory guidance on how digital therapeutics will be regulated when used in conjunction with medicinal products

Key questions:

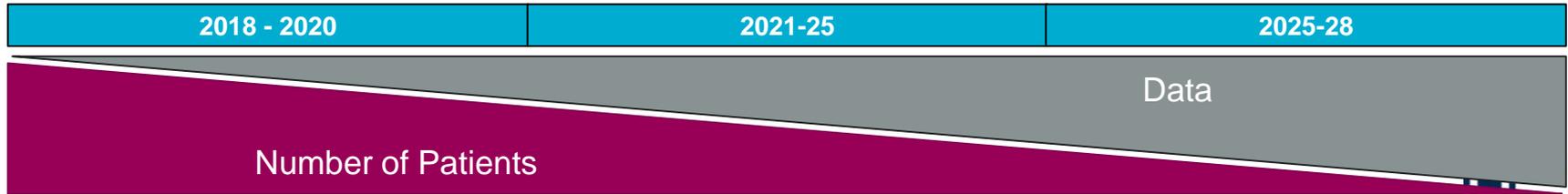
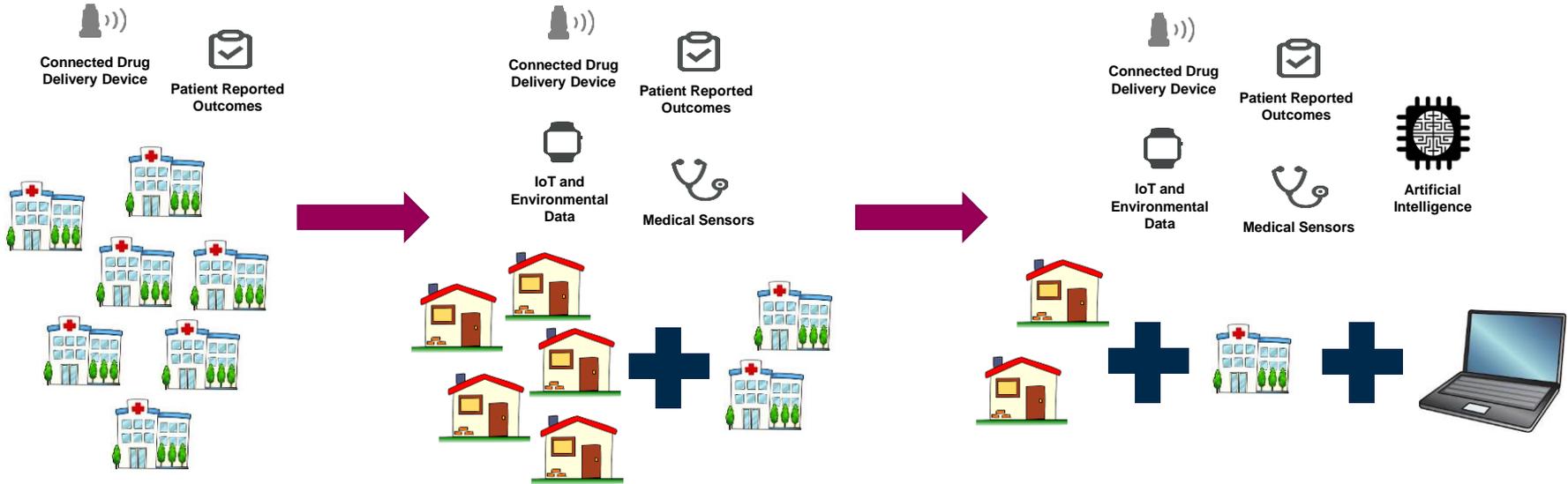
- How to incorporate digital tools into clinical studies?
- What are the routes to regulatory approval?
- What are the clinical data/information expectations to support regulatory approval?
- How will post market changes be managed?



Clinical Trials

Digital Therapeutics in Clinical Trials

Fewer patients - Enhanced insight



Digital Therapeutics Opportunity

Improve the development, efficacy and usage of new medicines

Improve
Patient
outcomes

New
medicines
to patients
faster

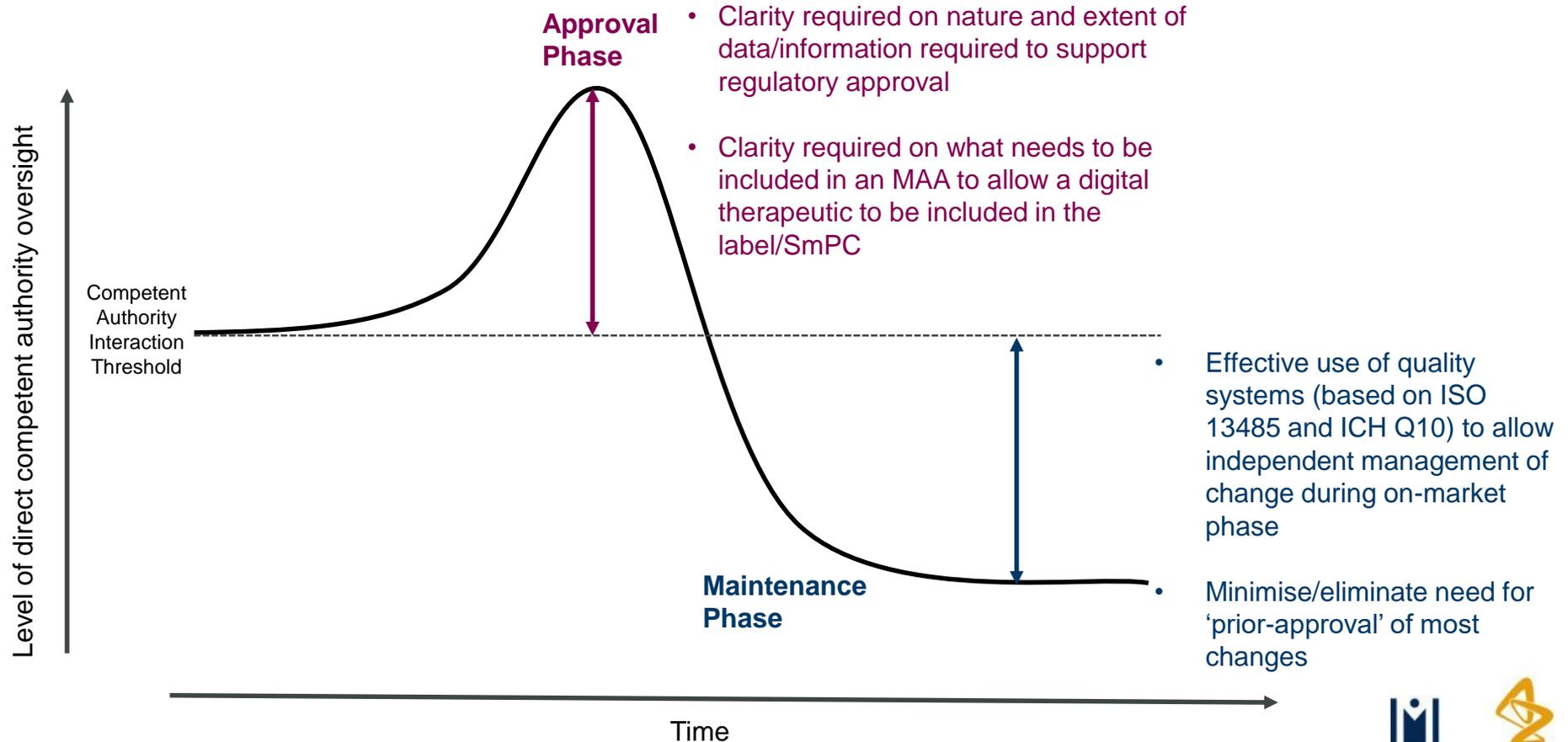
Examples of future Digital Therapeutics

- Precision Medicines – correct dose at the correct time for everyone!
 - New insights in disease progression
 - Predict and capture disease flares and changes so they can be mitigated in real time
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- Reduce need for study visit and follow-up; making trials more efficient and easier to execute
 - The increased frequency of data collection will improve data accuracy and reduce study sizes
 - Identify safety issues earlier to stop treatment or balance dose for those who need it
 - Integrate efficacy, safety and pharmacokinetics in preclinical studies
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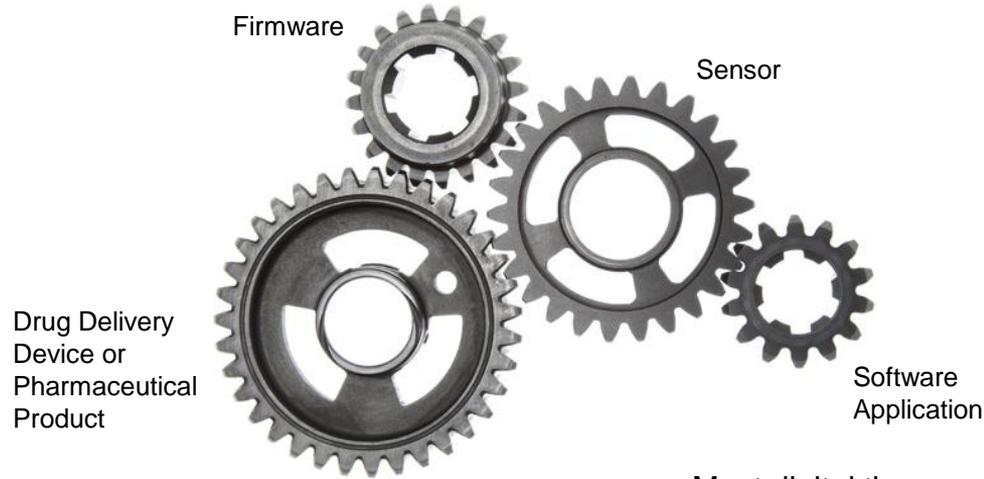


Approval and On-Market

Proposal – Initial Approval & Maintenance Phase

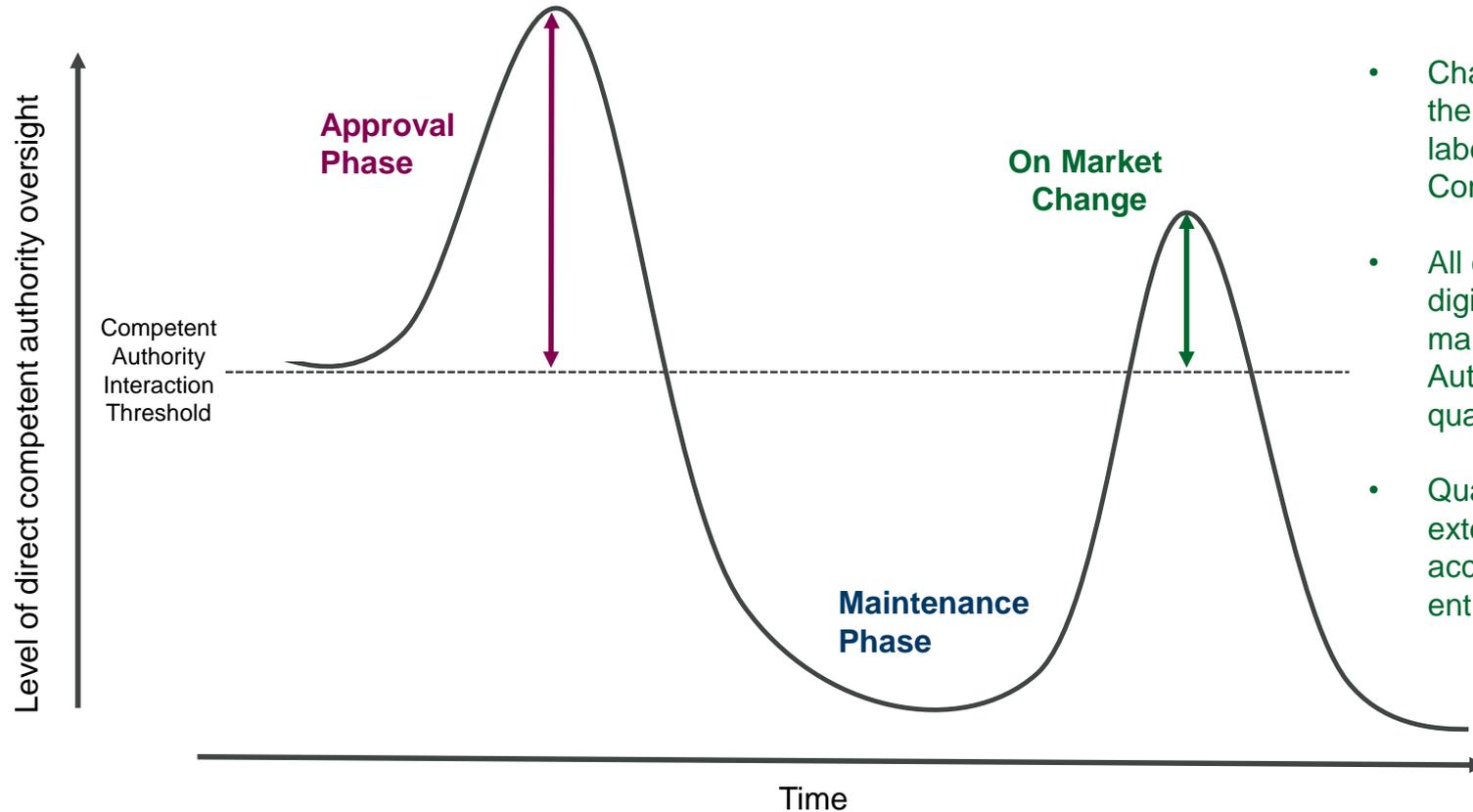


Key Challenge – Change Management



- Most digital therapeutics (in particular apps and other software, including their operating systems e.g. iOS, Android) are updated on a frequent basis
- Cadence of change does not match the medicinal product regulatory framework
- Increasingly problematic as a digital therapeutic becomes an intrinsic part of the overall product – inclusion within the label/SmPC

Proposal – On Market Change



- Changes to the digital therapeutic that affect the label/SmPC would require Competent Authority review
- All other changes to the digital therapeutic would be managed via the Marketing Authorisation holder's quality system
- Quality system is subject to external audit by a suitably accredited independent entity (e.g. Notified Body)



Digital Therapeutics: How to regulate the treatments of the future?

Recommendation

Encourage collaboration (e.g. workshop) between regulatory agencies and industry to develop guidance on:

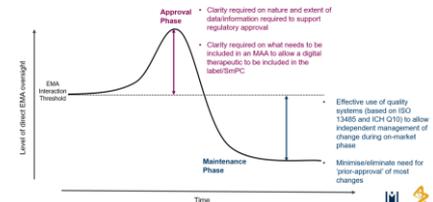
How to incorporate Digital Therapeutics into clinical studies



How to enable Digital Therapeutics to be included as part of the medicinal product label



Proposal – Initial Approval & Maintenance Phase



Management of on-market changes

