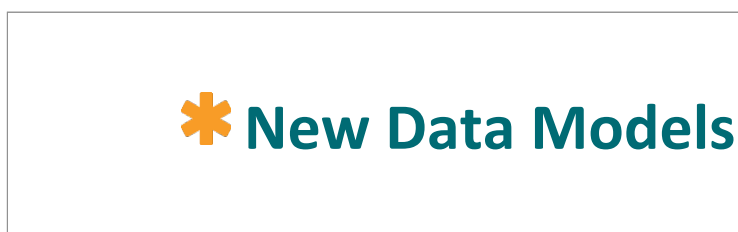
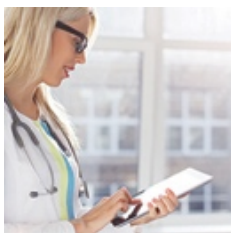


# Better Science, Better Health: New Healthcare Models

## New Data Models: Managing Uncertainty and Leveraging New Sources of Evidence

**Author:** Sabine Atzor \* **Date:** 27 Oct 2015 \* **Version:** Final



# From paradigm shifts for clinical evidence generation ...

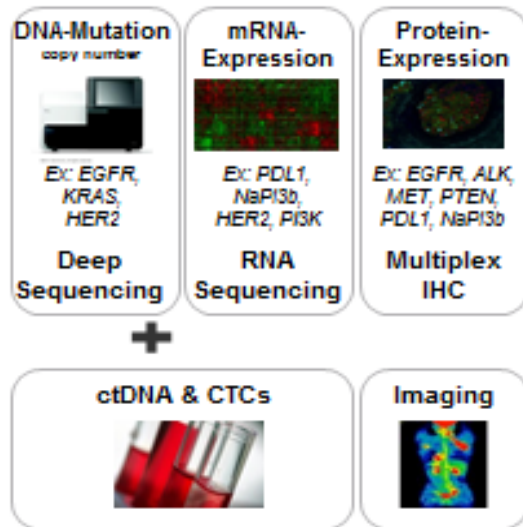


***“Basket Trials”***



***“Umbrella Trials”***

# ....to a new era of data generation



## Genomics england



Published on FierceBiotechIT (<http://www.fiercebiotechit.com>)

### Number of clinical trials to use wearables nears 300

September 16, 2015 | By Nick Paul Taylor

In recent years, the use of wearables in clinical trials has gone from being an attractive but untested idea to an emerging part of the research toolkit. Now, *Bloomberg* has tallied up just how many trials are building the devices into their protocols: 299.



# Medicines Adaptive Pathways to Patients

## MAPPs



- prospectively planned, adaptive approach to bringing drugs to market
- starting from an authorised (eventually “niche”) indication
- iterative phases of evidence gathering and progressive licensing adaptations
- balancing timely access for patients with the need to provide adequate evolving information on benefits and harms.

### Transition from...

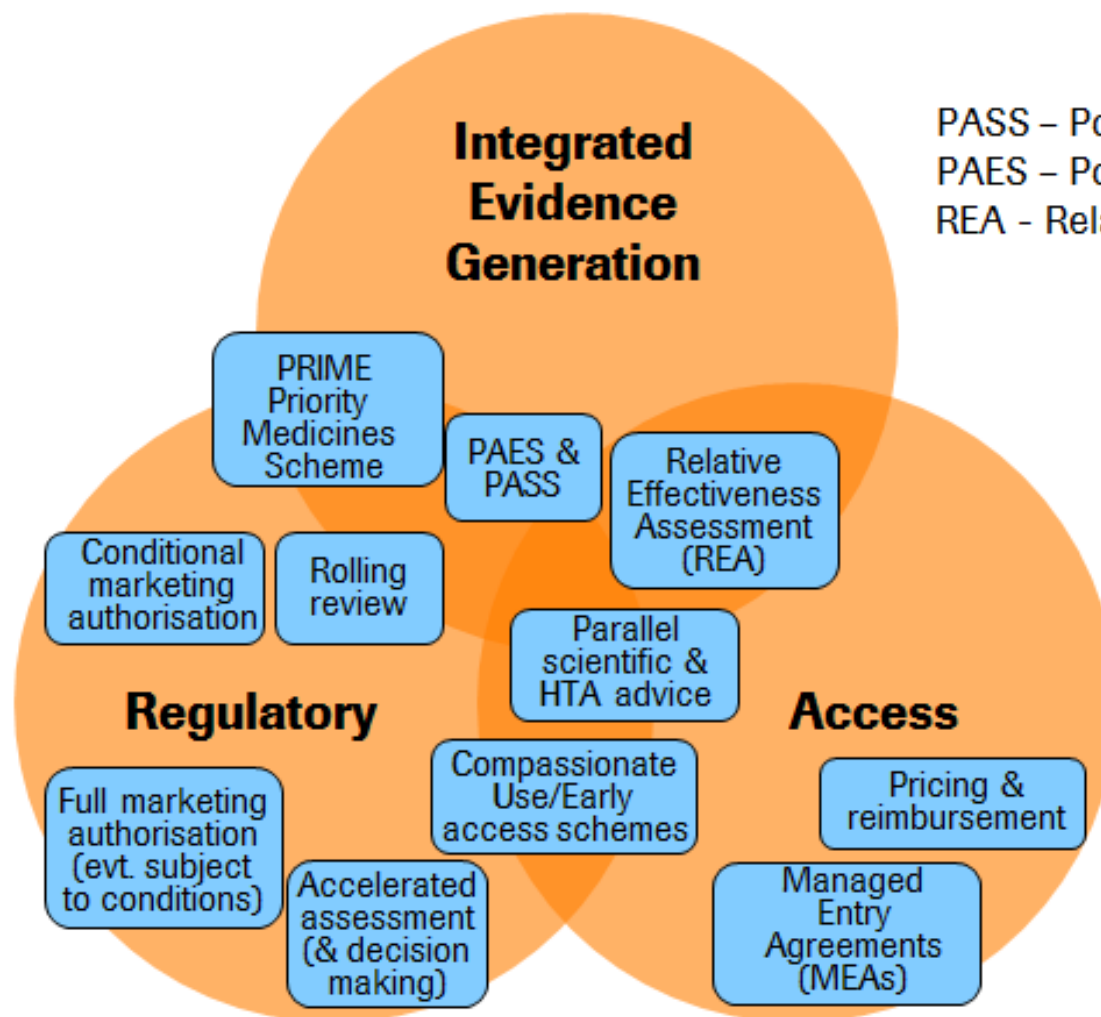
- Magic moment
- Prediction
- RCT only
- Big populations
- Focus on licensing
- Regulators/ industry
- Open utilisation



### To...

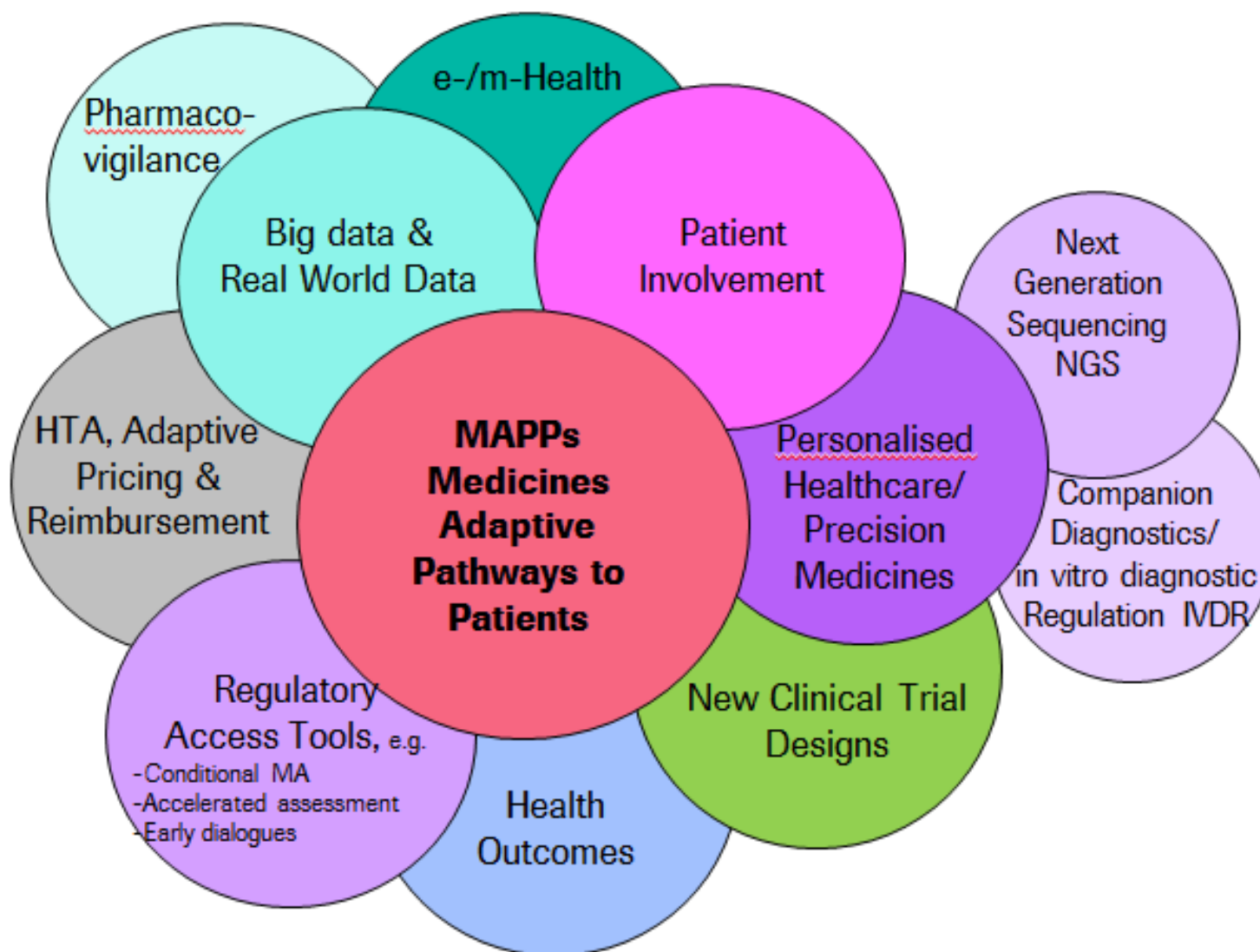
- Life-span management
- Monitoring
- Toolkit for evidence generation
- Small populations
- Focus on patient access
- Regulators, patients, industry, HTA bodies, payers
- Managed utilisation

# MAPPs – Connecting Tools and Stakeholders



PASS – Post Authorisation Safety Studies  
PAES – Post Authorisation Efficacy Studies  
REA – Relative Effectiveness Assessment

# MAPPs – Connecting the Dots



# Public Private Partnership – IMI

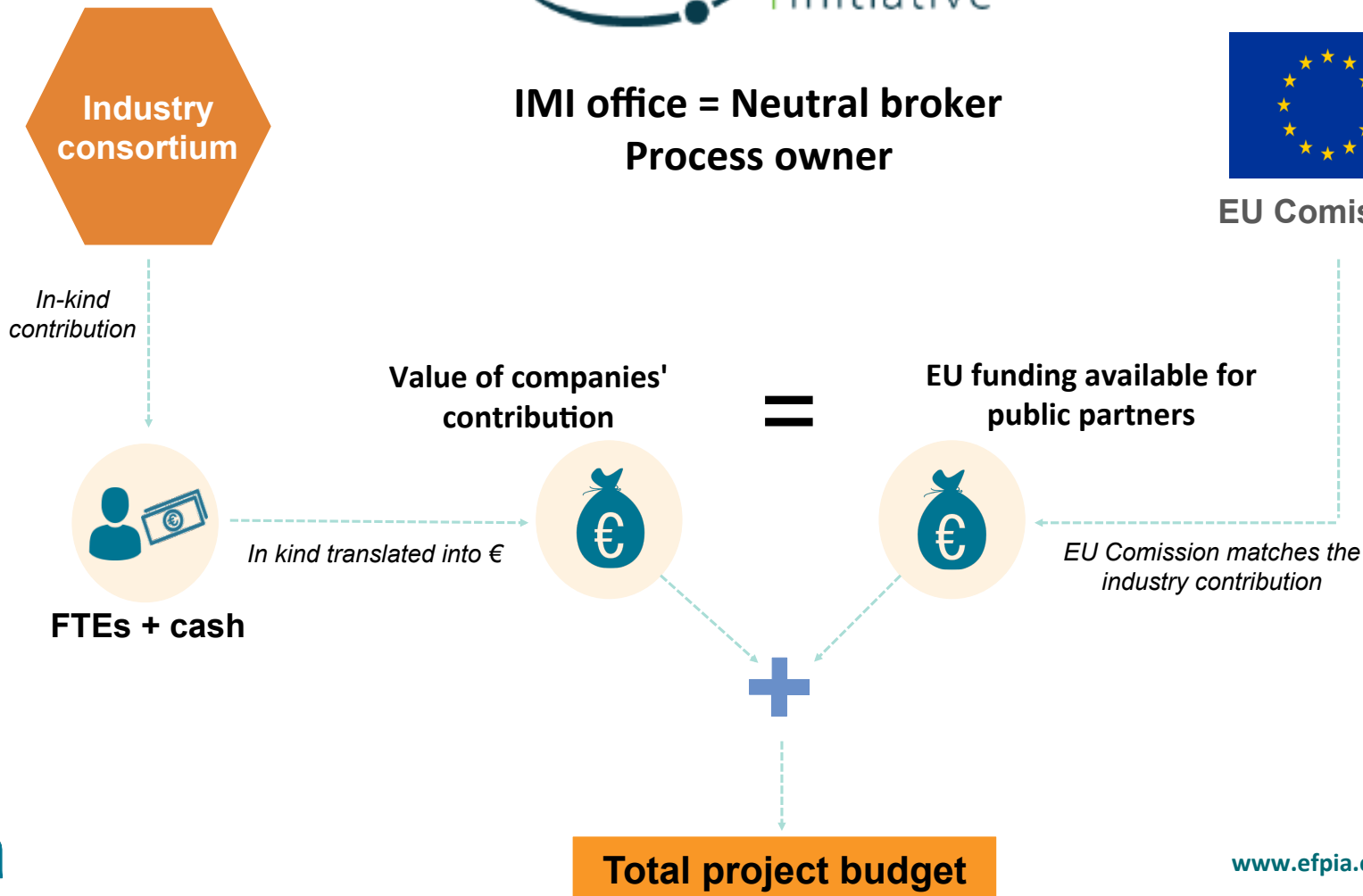
## *Address Bottlenecks of Innovation*



IMI office = Neutral broker  
Process owner



EU Commission

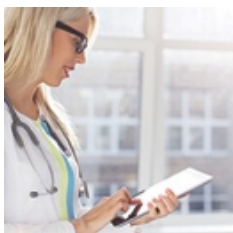






European Federation of Pharmaceutical  
Industries and Associations

Thank you!



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