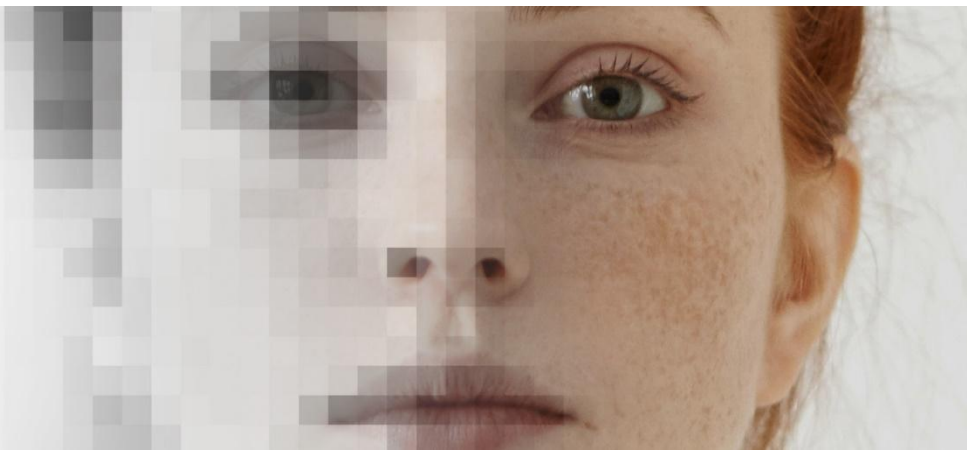


BBSW Sept meetup on RWD: RWD to inform R&D

Genentech PD-PHC analytics: James Chuo



Randomized control trial: what if, in a perfect situation, we can measure the true treatment effect (balance out confounders)
Efficacy- Can treatment work?



Real world data: who takes what at when and why (look at those differences)
Effectiveness- Does treatment work? Or Who would most benefit from the treatment

What site to select? For how many patients? How soon we can get them?

Target population

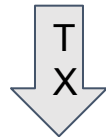
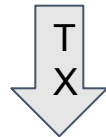
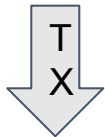
Treatment arm

Control arm

Who to compare to?

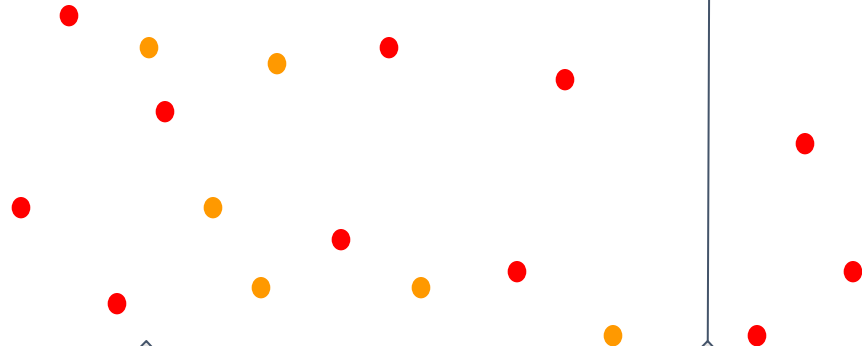
Treatment and standard of care protocol?

What's the outcome? And when to evaluate?



Followup

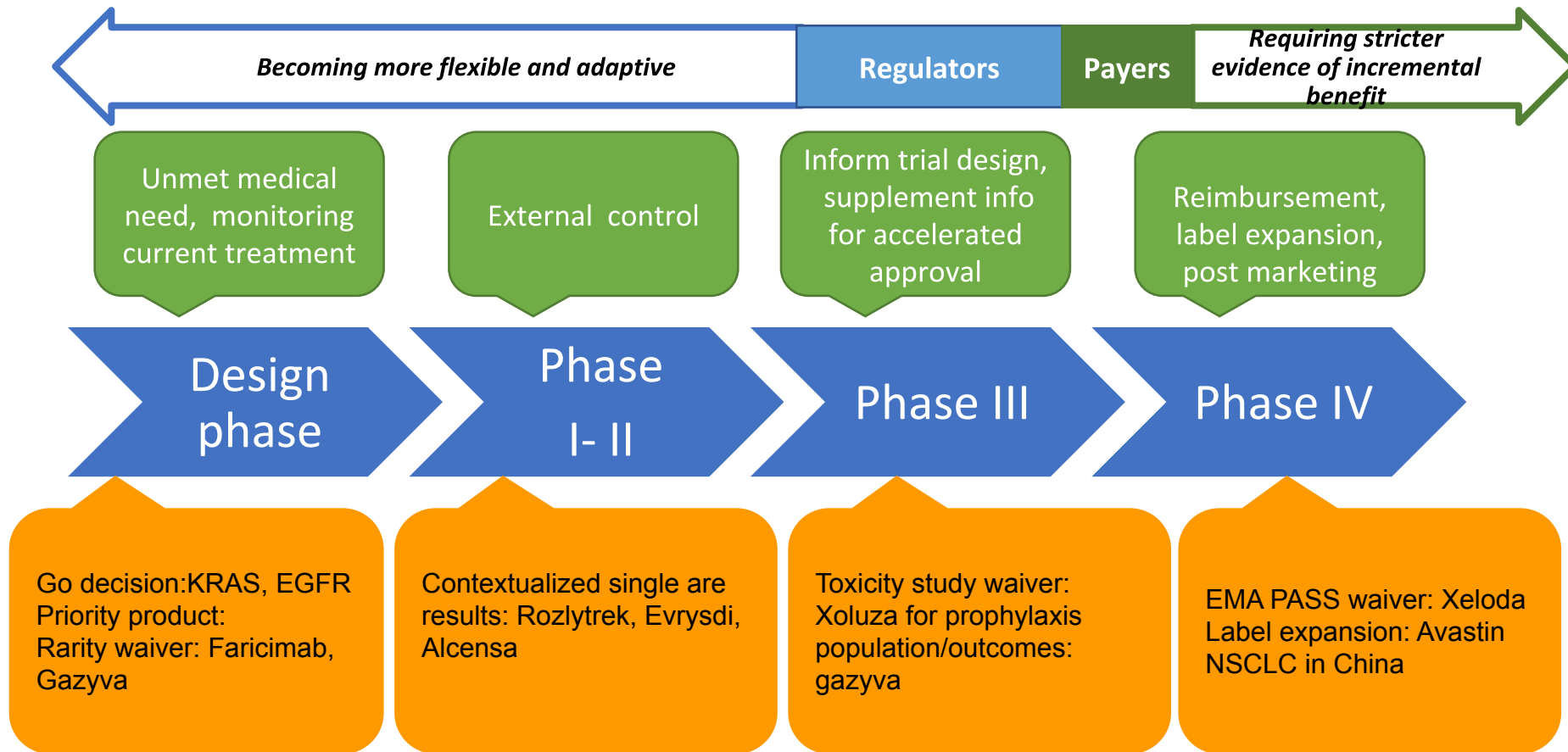
Endpoint evaluation



Common sources of RWD

Data type	Pros	Cons
Registries (e.g. rare disease registries)	Fit for purpose	Limited sample size and coverage
Medical claims (e.g. MarketScan, Pharmetrics)	Great coverage, enrollment information	No lab results and clinical outcomes Usually significant time lag
Electronic Medical Records (e.g. Optum, Flatiron)	Labs, vitals, treatment ,clinical outcomes	Limited coverage, no enrollment info

Using RWD to accelerate Product development



Knowing the heterogeneity

- ❑ Regional differences on patient characteristics and standard of care
- ❑ Identify underserved population- inclusive research
- ❑ Right treatment for the right patient

Personalized healthcare?

