Diversity and inclusion in clinical trials – a scientific need and an ethical obligation

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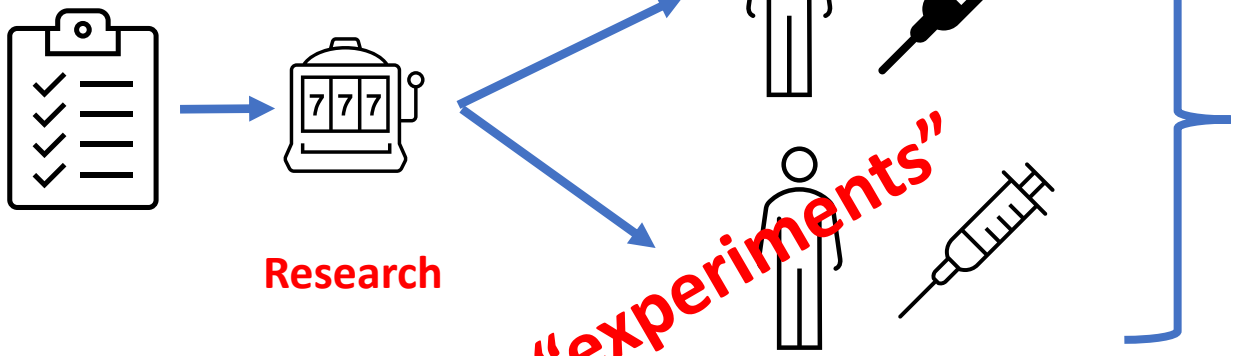
Regulation versus reality

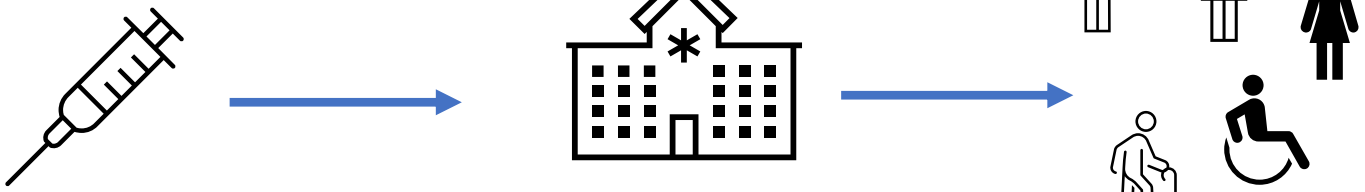


Research

Healthy, homogenous participant population:
-High internal validity
-Lower safety risk

Benefit/risk for a well-characterized population

Both are "experiments"



Routine care

Real-world diversity
-Age extremes
-Comorbidities
-Ethnic diversity
-Compliance and health literacy

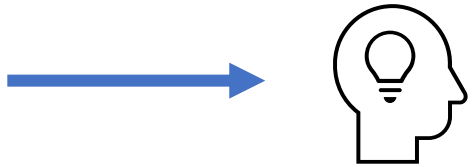
Mixed with less resources in daily clinical practice

ANNEX I

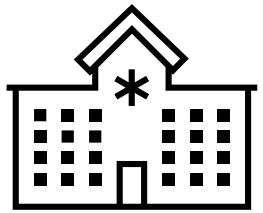
SUMMARY OF PRODUCT CHARACTERISTICS

clearance). Hydration should be maintained and serum creatinine levels monitored periodically. Administer IMBRUVICA to patients with severe renal impairment (<30 mL/min creatinine clearance) only if the benefit outweighs the risk and monitor patients closely for signs of toxicity. There are no data in patients with severe renal impairment or patients on dialysis (see section 5.2).

Only if benefit/risk is positive



How will HCPs know?



Several n=1 like experiments every day
-No formal evaluations
-No systematic data-capture

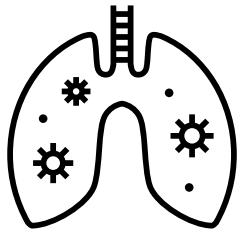
Eventually data will (hopefully) be collected but in an inefficient way
- Missed opportunities for patients
- Unnecessary toxicity

We need more diversity in trials , for example

- Careful relaxation of in/exclusion criteria
- Small sub cohorts in main studies
- Fixed enrollment targets

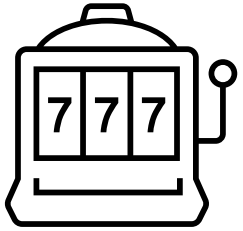
To make better the science for the broader society
- PK/PD in more patient subgroups
- Safety across different populations
- Benefit/risk for better informed decisions

Inclusion provides equal opportunities



Addressing serious unmet medical needs is a key priority in medical research
Unmet needs are typically not confined to:
-age
-ethnicity
-comorbidity
-residency

Most unmet medical needs are universal

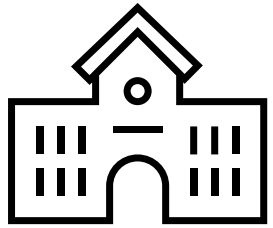


Some patients will view trial participation as an opportunity:
- Potentially effective therapy (no promise of positive benefit/risk)
- Access to therapies that are not reimbursed
- Contribute to research and future patients

The hope and opportunity should not per default be confined to specific patient populations

Initiatives and structures that promote equity is needed
Some patients have special needs that should be addressed, for example
- Travel for patient and family to site
- Language barriers
- Poor health literacy

Obstacles – from academic/clinician and ethics perspectives



From academic/clinician perspective:

Investigator trials –> Regulatory authorities may require stricter in/exclusion criteria for safety reasons – defensive approach can also potentially harm

Industry trials -> Protocols are finalized and sometimes approved before investigators are involved. Typical advisory boards may not focus on inclusion

From an ethics perspective:

Investigator trials –> Regulatory authorities may require stricter in/exclusion criteria for safety reasons – defensive approach can also potentially harm

Industry trials -> Protocols are finalized and sometimes approved before investigators are involved. Typical advisory boards may not focus on inclusion