Agence nationale de sécurité du médicament et des produits de santé

Actual process in Europe and USA- What is the futre need?

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September 29
Vienna

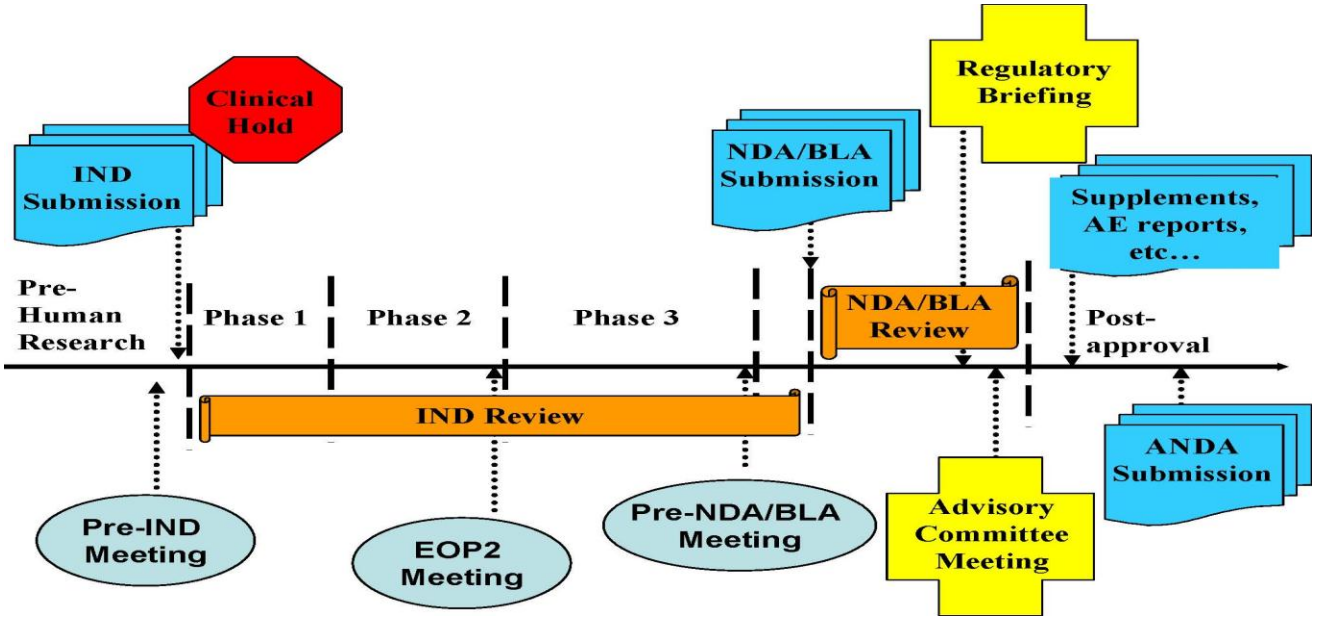
Only personal views.

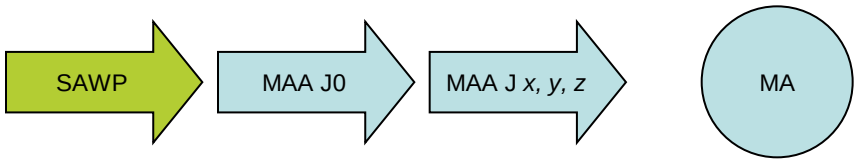
So…

Don’t complain to EMA or ANSM about me

Complain to me about me!

US/EU
Rolling Assessement / Stepwise Process





US / EU
One process / 25(+1+2) cultural backgrounds

- US
  - responsibility, accountability, respective roles of regulation and private initiative relatively homogeneous.

- EU
  - UK experimental approach: '*It works even if I do not precisely know why and how*'.
  - FR theoretical approach: '*It works in practice, but is it going to work again in theory?'*

Let’s have a look at conditional approval

Accelerated review, anticipated approval

Not a reward for promising results

Rather a punishment/ immature data

Let’s have a look at endpoints, designs

ORR sometimes acceptable even in uncontrolled trials

PFS could be an indicator of benefit and/or a surrogate for OS

Guidance on NI trials: margin with ref to placebo

Iressa 1st MAA, Revlimid/MDS,

OS first endpoint

PFS if indicative of benefit

Guidance on NI: margin with ref to active control

Do Agencies Speak to Each Other?

- Common Scientific Advices
- Coordinated MAAs
- Monthly Teleconferences

- Should we go further ????

MERCI POUR VOTRE AIMABLE ATTENTION