





NO

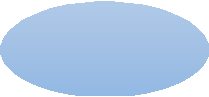




NO



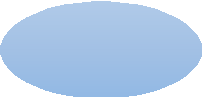
PS involving companion diagnostics



Scientific research-use only IVD



YES



CE marked IVD

YES

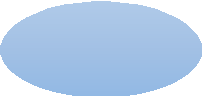


NO



YES

NO



PS within intended

purpose

Using only left-over samples

Simplified notification via DB

NO

No application or notification required





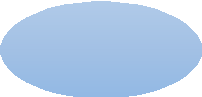


NO





YES



Additional burdensome procedures?

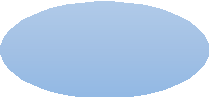
# YES



Does not fall under the IVDR



YES



Invasive sample-taking

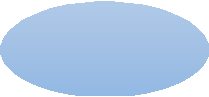
NO NO OOOO



YES

Application via RZPRO

Notification via RZPRO



Interventional PS and/or other risks for subjects?



YES





NO

IVDR - Regulation (EU)2017/746 PS – Performance Study

RZPRO – Registry of medical devices

IVD – *In vitro* diagnostic medical device

DB – Data Box