

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