

Notification for Medical and Pharmaceutical Professionals

ANNOUNCEMENT BY THE FEDERAL MINISTRY OF HEALTH AND THE PAUL-EHRLICH-INSTITUT

dated 29 July 2022

Non-interventional studies with authorised vaccines

Blood sampling and non-invasive testing, which represent minimal risk and burden for the data subject, are part of normal clinical practice in the following studies:

- a. studies with a vaccine authorised for the prevention of an existing or imminently threatening communicable disease, and
- b. if the vaccine is needed to ensure the supply of the population with vaccines against an existing or imminently threatening communicable disease.

These studies can thus be carried out as non-interventional studies within the meaning of section 4 paragraph 23 sentence 2 of the Medicinal Products Act (Arzneimittelgesetz). Undergoing an approval procedure for conducting a clinical trial is not required in these cases.

Consent for conducting the non-interventional study from the person concerned or their representative must be included.

