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. 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 legal representative must be included.