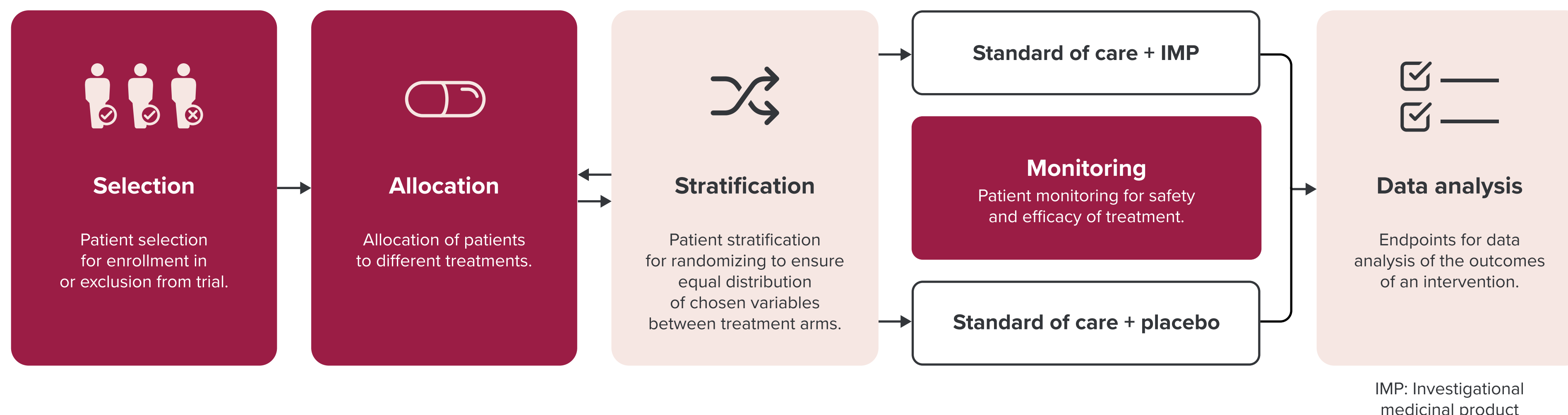


Wondering if the assay you use during your clinical trial is subject to IVD legislation ?

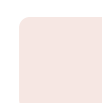
All assays with a medical purpose within the clinical trial are considered an *in vitro* diagnostic medical device (IVD) and subject to the legislation, also known as IVDR. The processes responding to these criteria are highlighted in the two-arms blinded clinical trial schema below as an example.



Exploratory assays for which correlation with clinical parameters is investigated retrospectively without having an impact on patients' treatment are not subject to IVDR.



Assays performed for these processes are used for medical management decisions of trial subjects – likely considered IVDs



Assays performed for these processes are likely not impacting the medical management of trial subjects – not considered IVDs

Image adapted from MDCG 2022-10 Q&A on the interface between Regulation (EU) 536/2014 on clinical trials for medicinal products for human use (CTR) and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR), Version May 2022.

Establishing your patient selection strategy? Developing a companion diagnostics (CDx)?
Our team of experts can help you identify and assemble required quality and regulatory deliverables.