

Phase IV Trials and Non-interventional Studies

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After the authorisation of a new drug further studies are initiated to further investigate its effectiveness and safety. They are summarized under the term Post-authorisation Study (PAS), which is any study conducted within the conditions of the approved Summary of Product Characteristics or under normal conditions of use. This covers both interventional clinical trials (Phase IV) and Non-interventional Studies (NIS). An overview is provided about the various designs and (German) regulations of PAS. Besides the efficacy, the safety of a registered drug is a major focus of a PAS as it is possible to document and to evaluate larger patient populations than in the preceding Phase I to III trials. In addition, subgroup populations, daily usage or the optimization of the therapy may be investigated in a PAS. However, according to the design chosen the informative value can be limited compared to clinical trials of the former phases, in particular if it is not a controlled study. The potentials and limitations of a PAS will be presented from a practical and methodological point of view. In summary, the different variations of a PAS are valuable tools in clinical research provided the PAS is well-designed, well-conducted and well-interpreted.

