

## Requirements for IHPBA Trials



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As regulative requirements for pharmaceutical trials are getting more and more complex (e.g. European Directive on the Conduct of Clinical Trials), the first generation of IHPBA Trials should be solely based on the comparison of surgical techniques in order to be able to establish a strong network of IHPBA Trial Units. Thus, at the beginning, important unanswered surgical questions should be answered in IHPBA trials, such as “drainage versus no-drainage”, “hepatic inflow control versus no inflow control”, “reconstruction technique A versus reconstruction technique B”, etc.

### Requirements of IHPBA Trials

- Only high quality study protocols should be selected in order to have an impact on scientific and surgical world and to prove that HPB surgeons are strong leaders in performing trials.
- The concept of “clinical equipoise” should be fulfilled by the given scientific question to be answered in the trial, meaning that “the requirement is satisfied if there is genuine uncertainty within the expert medical community – not necessarily on the part of the individual investigator – about the preferred treatment” (Freedman, NEJM 1987).
- The background and the importance of the trial idea should be clarified, if possible on the basis of a systematic review of the given scientific literature.

- A strict adherence to defined structures in the development and conduct of IHPBA Trials is mandatory – e.g. the proposed step-by-step process of IHPBA Trial Proposal – in order to keep optimal transparency and to further motivate HPB surgeons to participate.
- Feasibility of a given trial (sample size, recruitment numbers, appropriate financial support, no competitive studies, established infrastructure and logistics) is one of the major goals for the first IHPBA Trials.