Jorunn Tverland

Specific considerations of in vitro diagnostics

Background: In vitro diagnostics (IVDs) include products used to collect, prepare or examine tissue or other biological materials after they are removed from the body to diagnose patients to receive proper treatment. Correct and timely diagnosis is important to ensure that patients receive the optimal treatment as quickly as possible.

Learning objective and purpose: By the end of the presentation, participants will know the specific considerations one needs to take into account when conducting clinical trials within IVDs, and how these differ from other medical devices.

Objective: To describe the major considerations when conducting IVD trials, exemplified by retrospective observational IVD trials in cancer using leftover human tissues that are not individually identifiable.

Method: As part of onboarding in my new position in IVDs I have searched literature to gain new knowledge in the field of IVDs.

Results: During my research in the field of IVDs I have identified four interesting areas to investigate and discuss further; Safety, Ethical Consideration, Guidelines/Regulatory requirements and Operational

Safety: Within IVD trials, patient safety always comes first. Patient safety in observational IVD trials differ however from other clinical trials when the tissue used in the trial is de-identified leftover tissue obtained for the patient's own medical need. Ethical Consideration: IVD trials are conducted in accordance with the Declaration of Helsinki and ICH GCP where relevant, but IVD trials using left over tissue can often be conducted without Informed Consent. Guidelines/Regulations: In IVD trials ICH GCP provides useful reference regarding proper conduct of trials. ISO 14155 states that it does not apply to IVD devices. Even if IVD trials are exempt to some regulatory requirements because of low risk for participating subjects, regulatory requirements and laws are followed for trials that support applications to FDA and other regulatory bodies. Operational: The Planning, reporting and archiving phases in IVD trials are similar to other clinical trials. The conduction phase is however different as IVD trials are mostly of short duration, test site is in control of the study, there are no patient FU visits or (s)AE reporting, and no patients that can get LTFU.

Conclusion: Personalized medicine is becoming increasingly important and high quality IVDs are crucial to ensure the individual patient is diagnosed correctly and timely so he/she receives the most optimal drug as quickly as possible. Therefore, I can only see an increasing need of effective and sensitive IVDs and I am happy and proud to contribute to IVD trials that improve life quality and save costs of unnecessary and ineffective treatment.