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Table 1: Critical differences between medical device studies in the EU and the US

	Europe	US
Clinical investigation approval	All clinical investigations need to be approved by ethics committees (EC) and notified to the competent authorities (CA) of all involved countries – the responsible CA for a medical device investigation may not be identical with the CA for a pharmaceutical study. If a device is CE marked and used according to label claims, notification of the CA is usually waived, but not approval by an EC.	An Investigational Device Exemption (IDE) is necessary and has to be granted by the FDA before the start of the study. The FDA foresees several levels of regulatory control which depend on the risk level of the device, therefore clinical studies are divided in significant or non-significant risk device studies (7). For significant risk device studies, approval by an institutional review board (IRB) and the FDA is required. For non-significant device studies only IRB approval is necessary. Several exemptions from the IDE process for clinical studies are listed in §812.2(c) of 21 CRF.
Good Clinical Practice Standard	The applicable Good Clinical Practice (GCP) Standard for medical device investigation is laid down in ISO 14155 (2011). This newly defined GCP standard is to a large extent similar to the ICH-GCP standard used for pharmaceutical studies. Adherence to the principles laid down in the Declaration of Helsinki is mandatory (8).	The applicable GCP standard for medical device studies is essentially the ICH-GCP standard applicable to pharmaceutical clinical studies. Also adherence to the Declaration of Helsinki is a strict requirement.
Objective	The objective of the clinical investigation is to demonstrate *safety and performance* within the scope of the intended use, and conformity with claims, of the investigational medical device.	The objective of the clinical study is to demonstrate *safety and effectiveness* of the investigational medical device.
Essential documents	The essential documents for a medical device investigation are essentially similar to the ones required for a pharmaceutical study. However, the required contents and the terminology may be different for similar documents (See ISO 14155(2011) Annex E, ICH E6 GCP, Section 8 (9) for an overview).	The essential documents for a medical device investigation are essentially similar to the ones required for a pharmaceutical study.
Adverse events	Monitoring of adverse events and adverse device effects during a medical device investigation cannot be limited to the investigation subjects but needs to include third parties, such as the operators of a device and even bystanders.	Adverse events are monitored for study subjects only and should be reported to the sponsor. Records need to be kept for all complaints and adverse device effects, whether anticipated or not (10).
Serious adverse events (SAE)	All SAE in a medical device investigation occurring anywhere in the world, regardless whether judged to be linked with the device or not, need to be reported to the competent authorities of all European countries in which a clinical investigation is being conducted.	See UADE regulation.
Unanticipated adverse device effects (UADE)	See SAE regulation.	UADE must immediately be evaluated by the sponsor and if an UADE suggests an unreasonable risk to study subjects, then investigations have to be terminated as soon as possible, which should be no later than 15 working days after having received notice of the UADE. UADE have to be reported to the sponsor and the responsible IRB's no later than 10 days after the investigator had learnt about it (11). The sponsor shall report evaluation results of UADEs to IRBs, the FDA and all participating investigators within 10 working days after having learnt about it (12).
Medical device accountability	Device accountability during a clinical investigation does not only involve recording stored and dispensed devices, but most importantly also accounts (where applicable) for the return of used devices to the investigative site and the sponsor. To ensure complete return is essential for the manufacturer to be able to investigate the device in case of adverse events.	Device accountability during a clinical investigation does not only involve accounting for stored, dispensed and returned devices, but also recording device repair, adverse device effects, complaints and device disposal, including reasons for and methods of disposal.
Risk evaluation	Risk associated with the investigational device must be evaluated, in accordance ISO 14971, prior to conducting an investigation (13). The risk analysis is to include an objective review of published and available unpublished data. *A clinical investigation is only justifiable if the risks related to the device and the associated clinical procedure are at least balanced against the potential benefits to the subjects.* A summary of the risk analysis must be included in the investigator's brochure. The clinical investigation plan must address risks and benefits of the investigational device and any related procedure(s).	Risk associated with the investigational device must be assessed prior to conducting an investigation. The study protocol must discuss the risk in relation of the inherent risk of the disease to be treated, the theoretical and the reasonably foreseeable risks of the investigational therapy, and include an overall risk benefit assessment. Benefits from participating in the study should be clearly defined and may also include the benefit of enhancing the knowledge about the disease or therapy. *A clinical study is deemed to be justified if the benefits outweigh the risks.*

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