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Advancing Medical Device Clinical Investigations: Overcoming Challenges

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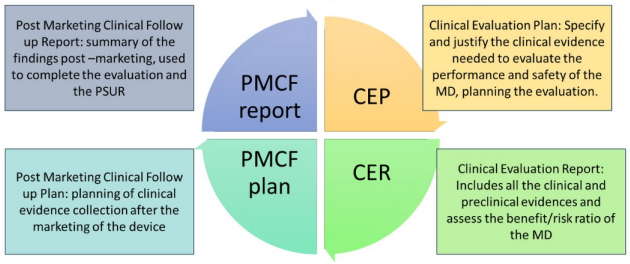
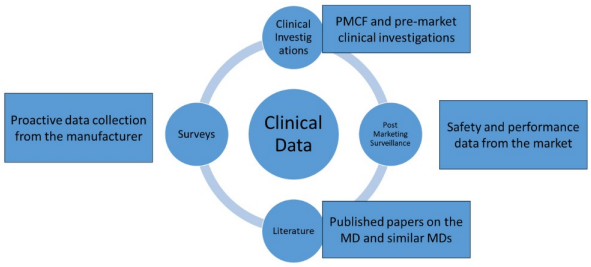
Clinical Evaluation according to MDR (EU) 2017/745

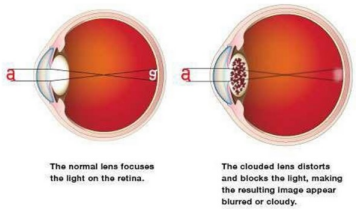


Increased need of clinical data



Implantable Intraocular Lenses

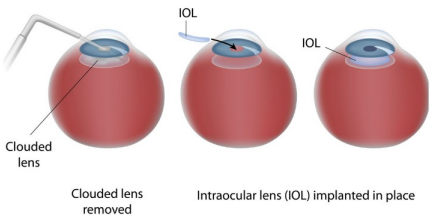
Cataract is a clouding of the lens or an opacity within the lens which leads to a decrease in vision.



INCIDENCE

AGE GROUP (YEARS)	LENS OPACITY (%)
50 – 59	65
60 – 69	83
70 – 79	91
> 80	100

Cataract Surgery



Main Challenges for clinical investigations with IOL

1. The **identification of clinical sites** for clinical investigations in implantable MD is challenging due to:
   a. Although cataract surgery is often perceived as routine, it still requires clinical investigation to ensure safety and performance of implantable devices;
   b. The assessments required by clinical investigations go beyond standard practice, increasing visit duration and frequency;
   c. The benefit for the patient is limited;
   d. The longer follow up usually discourages the patients and the investigators.

How to react:
   a. Conduct a feasibility assessment;
   b. Establish long-term partnerships with experienced and motivated clinical sites;
   c. Engage investigators and patients to validate the study design and ensure it is feasible and optimized.

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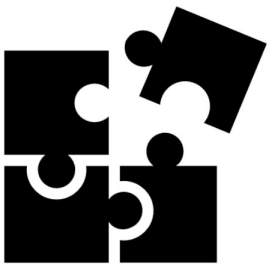

2. Identification of **long term clinical evidences**:
   a. **PMCF clinical investigation**, well designed and properly powered, with a long follow up (at least 12 months);
   b. **Annual literature search** and materiovigilance data from the post-marketing surveillance;
   c. **Pro-active data collection** through 10 years-surveys.

3. The **clinical service provider** plays a critical role in the success of the clinical investigation by offering specific expertise in ophthalmology, experience with IOLs, trained CRAs, and a solid understanding of ophthalmic biometric data.

How to manage:
   1. Identification of the proper CRO, providing training if needed;
   2. Sponsor personnel should be present at the SIV, attend the first monitoring visit, and have access to the eCRF for proper monitoring;
   3. For highly innovative devices, sponsor personnel should attend initial implant procedures to support investigators and ensure correct device use.

In Conclusion: Plan for Success!

The successfull clinical evidence collection is linked to
•Excellent planning;
•Continuous and proactive collection;
•Integration between clinical investigation and post-marketing data;
Collaboration between clinical investigator, CROs, Sponsor and patients

PSUR=Periodic Safety Update Report, SIV=Site Initiation Visit, CRA= Clinical Research Associate, eCRF= electronic Case Report Form