Bionical Emas

Fact Sheet

Four things to think about: PVG in EAPs

By Nisha Vora

- Compassionate Use
- Named Patient Use
- Expanded Access Use
- Managed Access

These are all different types of Early Access Programs (EAPs) which deliver investigational treatments to patients with life-threatening conditions, who have no alternative treatment options available.

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Here are four things to think about when considering pharmacovigilance (PVG) for EAPs.

Some regions require EAP ICSR submissions to follow clinical trial reporting rules whilst others consider EAP ICSRs to be reported per post market reporting rules.

In addition to inclusion of EAP safety information in DSURs/IND annual safety reports, some regions may require an annual report specifically on use within that EAP, for which a section on safety observations will be required.

Safety data collection requirements vary across the different types of EAPs and geographic regions. In Europe, this even varies across Member States.

Bionical Emas are uniquely positioned to support you with your EAP pharmacovigilance requirements; Our PVG function work closely with Regulatory Affairs and the Bionical EAP division to ensure we have a thorough understanding of the regulatory basis of the EAP so that we can use our expertise to deliver a tailored PVG service.

Cross reporting may be required, for example, FDA consider IND safety reports to be important safety information, regardless of whether the report originated from any other IND in which the Sponsor is providing the investigational drug.

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