Bionical Emas

Fact Sheet

A guide to the Development Safety Update Report (DSUR)

What is a DSUR?

A Development Safety Update Report (DSUR) is a concise yet comprehensive analytical report, presenting the assessment of risk and any changes, in accordance with previous knowledge of the safety of the investigational drug. The DSUR is **now a legal requirement** in the European Union (EU) and widely accepted by Regulatory Authorities outside of the EU including the FDA and Asia Pacific. The format widely accepted is in ICH E2F.

What is the goal?

- To review and assess the risks and any changes since previous knowledge.
- To provide a summary of any safety issues that could have an impact on the protection of clinical study participants.
- Summarise the current understanding and management of any identified and potential safety risks to exposed patients.
- Provide an update on the status of the clinical development program and study results.

When should a DSUR be submitted?

The report should be submitted at yearly intervals from the year of the Development International Birth Date (DIBD – the date of first authorisation of a clinical trial in any country worldwide).

Have you considered?

- Coordination of the DSUR with the Reference Safety Information (RSI) update.
- Harmonised submissions of the PSUR and DSUR each year since there can be overlap between the content of the DSUR and PSUR.
- There should be only one DSUR for one investigational drug (active moiety), regardless of different strengths, formulations and indications.

How can Bionical Emas help?

The DSUR can be a complex document but Bionical Emas have extensive expertise in house with 15 + years' experience in writing these aggregate reports, covering all elements of DSUR and other safety document development such as line listings.

Bionical Emas can provide a consolidated safety reporting system, together with the in-house expertise to produce an accurate report for the Regulatory Authorities and Regional Ethics Committees. Bionical Emas can produce DSURs as standalone projects, as well as part of a pharmacovigilance service for full service clinical trial programmes.

Why use Bionical Emas?

Having produced over 70 DSUR's/Annual Reports, all submitted on time and accurately, clients can be sure that their study DSURs are in safe hands with Bionical Emas.