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SAFETY ASSESSMENT

Environmental Risk Assessment of Human Pharmaceuticals

Services

- Global regulatory support
  - Preliminary testing (US)/ Phase I assessment (EU)
  - Tiers 1-3 (US)
  - Phases IIA and IIB (EU)
- Physicochemical testing
- Environmental fate
- Ecotoxicology

The environmental impact assessment of human pharmaceuticals can be a lengthy and involved process, potentially taking a number of years depending on the product and target market. Conducting an appropriate and integrated environmental testing program with Charles River eliminates unexpected delays in this stage of the approval process.

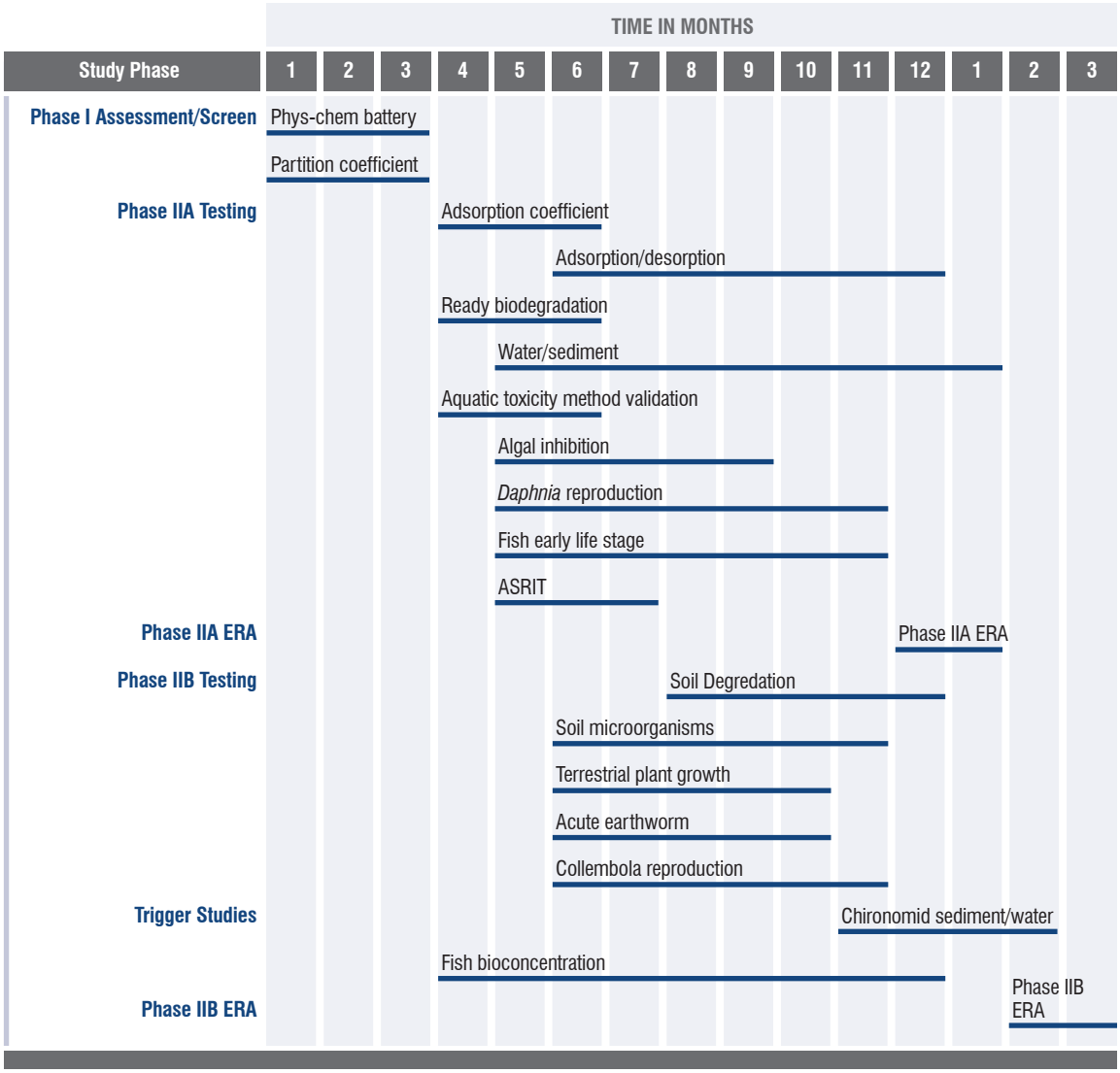
The impact of human pharmaceuticals on the environment, by provision of an Environmental Risk Assessment (ERA), is a current regulatory requirement in both the EU and US European Market Authorisation Application or a US FDA New Drug Application must contain an evaluation of the potential environmental impact of the drug substance, applying to both new and existing products with certain use variations. Legislation is also under discussion in other regions.

Charles River provides a comprehensive service in accordance with the existing guidance documents. We can arrange initial evaluation of potential environmental exposure and risk following review of usage patterns and available environmental effects data and phased refinement of the ERA. We can also liaise with authorities and consultants regarding the detailed design and scientific justification of any nonstandard tests that may be required.

With extensive experience in study design across multiple industrial sectors, our team has a thorough understanding of these unique regulatory requirements, from study design to the review and interpretation of data. We can assist clients in the pharmaceutical arena with the design of programs and studies tailored to the properties of their medicinal product.

EVERY STEP OF THE WAY

Environmental Risk Assessment for Pharmaceuticals Timeline



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