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## 4 Non-clinical and clinical safety assessment of biosimilar products

To gain regulatory approval, a biosimilar product not only has to be compared with an approved reference product, but has to undergo both clinical and non-clinical studies, together with a pharmacovigilance plan.

*Rakesh Dixit and Joerg Bluemel*

## 8 Managing concomitant medications in clinical trials

This article highlights the need for better management of the issue of concomitant medications in the interest of patient safety in global multicentre clinical trials. Many drug interactions are avoidable.

*Mark Dale*

## 11 Priority PASS

Post-authorisation safety studies (PASS) now have to take into account the new EU Good Pharmacovigilance Practices (GVP) legislation.

*Miranda Dollen and Kosta Cvijovic*

## 14 Reporting safety data electronically

More timely reporting of potential serious effects, coupled with the reduction of unnecessary reports, can best be done using modern analytical and visualisation tools in order to increase patient safety and reduce costs.

*Rick Morrison*