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Setting higher medical standards

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DG Sanco
Pharmaceutical Technology
European Commission

9th September 2010

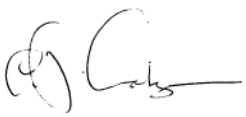
Dear Sir or Madam

Re: Draft detailed guidance on the collection, verification and presentation of adverse reaction reports arising from clinical trials on medicinal products for human use

The Royal College of Physicians (RCP) is grateful for the opportunity to respond to the above consultation. We would like to make the following comment.

We welcome the revision of the Directive and support attempts to simplify and rationalise the procedures for carrying out Randomised Controlled Trials (RCTs). Simplification of the Directive should encourage researchers and clinicians to undertake RCTs which are crucial to improving treatments in all spheres of medicine.

Yours faithfully



Dr Patrick Cadigan
Registrar