

# Preface

This book arose from a series of discussions of the International Society of Pharmacovigilance (ISoP), culminating in a strategic planning meeting in Berlin in 2012, with the Executive Committee members and all past-Presidents of ISoP present to talk about the future.

From the Berlin meeting, there was a common view that there were movements in society in general and medicine in particular that would affect the practice of pharmacovigilance. A long list of future issues that needed addressing was identified: ranging from the utilisation of richer data sources as a complement to case reports, to anti-counterfeiting measures, and the need for transparency of both assessment and decisions.

It was thought that over the last decade in particular, there had been a great increase in media attention paid to issues of drug safety. Also, there are an increasing number of stakeholders with active interests in different broad aspects of safety: all expressing views that the current system is not delivering optimally to improve therapeutics in clinical practice.

Perhaps the major concern is that a concentration on intrinsic problems with drug products means that there is not enough awareness and activity in improving patient care which will need a much more holistic view of risk and benefit in the use of drugs.

No one can be in any doubt about the magnitude of the tasks and changes needed to achieve better pharmacovigilance practices in the future. On the other hand, there is little doubt that the overall high level of iatrogenic illness must be addressed, nor is anyone complacent about the increasing costs of health care, partly due to medication issues.

Several ISoP members have been critical of the largely public health approach to pharmacovigilance – a top-down approach which respects neither the patients' needs and wishes, nor those of highly trained and much overworked professionals who take huge pains and responsibility to give individual patients the best care.

So it is that the idea of this book was born: Why not ask ISoP members to give their views on where pharmacovigilance should go, and what it should leave behind (at least in part)?

We are grateful to all the members of ISoP who have given up their time to talk to us and give us ideas and support. We are particularly grateful to the ex-Presidents and Executive Committee members of ISoP who have shared their thoughts with us. Most of all we are thankful to the chapter writers who have had the courage and imagination to express their thoughts about how the future might be better in pharmacovigilance, and taken the time to write it all down and to keep to deadlines (more or less!).

One person who deserves our special thanks is Sophie Spence, who is ISoP's administrative heart. Without her efforts in bringing us all together happily in Berlin and then supporting us tirelessly with all the correspondence, a few reminders (!), and general organisation, all would have been chaos and loss (at least for one of us – IRE).

You will see that the contributions vary in length and style, and that is deliberate. We did not want to be in any way restrictive, and we hope that this book is just the start of a dialogue that will bring in many more individuals and groups that can add their contributions to progress. We hope this can be done via a web-based version of this book, so that this work will be living for time to come – for the improvement of clinical benefit and avoidance of harm.

Finally, we would like to express our thanks to our ever cheerful, diplomatic and strong supporter who encouraged us to 'go for it' with this book, who is, of course, Nitin Joshi. Nitin has remained enthusiastic on the sidelines even after he recommended us to go ahead practically with the excellent publishing team from Springer, Prasad Gurunadham, Ellen Blasig and Cameron Wright, whom we also thank heartily. They have kept us on the straight and narrow pathway to the finished product, but miraculously made our job painless as well. David Elek at Springer also has been in the background and we thank him for his general support of this project.

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