While many stakeholders keenly await a clinical trial portal as a key element in the implementation of the EU Clinical Trials Regulation, recent years have undoubtedly seen major advances in the use of gateways or portals for making e-submissions. This edition’s focus is around electronic submission and the use of e-portals, with three themed articles describing veterinary submissions via the use of e-portals, a service provider’s perspective for available e-portals, and an article highlighting progress in Japan with the PMDA for eCTD submissions and the agency’s gateway. The use of gateways or portals for expedient submission of applications has, in the main, improved provision to the competent authorities internationally, compared with legacy times of paper or physical media-based submissions.

Readers may be familiar with some of the portals in use such as Eudralink, CESP, EMA Gateway and Web Client, but possibly less familiar with others described – EVWeb or portal initiatives for submissions in Japan. The articles presented provide a useful update in a fast-moving arena.

In the veterinary field, although there is much in common with human medicinal products, important differences are highlighted. The EU Veterinary Medicinal Product Database was originally established as a critical reference for pharmacovigilance reporting. However, this contains many historical inaccuracies that need to be resolved. This database forms part of proposals for a new veterinary medicines regulation, and is seen as a vital tool, both for pharmacovigilance and monitoring the use of antimicrobials.

An article from Katja Koesterke-Wagner offers a brief account of some of the history that has led to the current electronic submission practices and provides a useful list of some of the major web portals. The article also discusses the challenges of defining which elements are outsourced, and provides a practical and pragmatic view for considerations in the use of portals, as well as the need for careful planning with the use of this means of submission.

Masami Tamura and Hiroji Emoto describe the evolving situation in Japan and the PMDA’s updated implementation of the eCTD which incorporates the CDISC and SDTM standards for the transmission of study data, with the intent of increased analysis of the study data by the PMDA. Having embraced the new eCTD 4.0, the Japanese regulatory authority plans to begin pilot submissions in 2018. A gateway capable of accepting submissions at the PMDA electronically should be live in October of this year, with its use becoming compulsory in April 2020.

On the theme of technology and regulatory information management, colleagues at Veeva Systems present an account for mitigating risk by technology convergence. This highlights the importance of breaking down barriers among various functional and geographical groupings, often relying on disconnected technology where manual intervention is usually the means by which information is shared, to achieve a more uniform approach where all stakeholders are essentially working with the same information repository. Inevitably, to achieve such interoperability, there needs to be standardisation of data definitions and vocabulary. This need has given rise to IDMP (identification of medicinal products), the main driving force for which is the essential information sharing required to support effective pharmacovigilance.

A further article on veterinary medicines is provided by authors from the CMDv. They offer practical guidance on the naming of a veterinary medicinal product, and on the use of “standard terms” during the mutual recognition and decentralised procedures.

The output of two conferences – the first for the 9th European Generic Medicines Association Annual Pharmacovigilance conference in January 2016, and the second for the BIA/MHRA 6th Regulatory Conference on Accelerated Development and Access to Innovative Medicines to Patients, including the introduction of the EMA’s PRIME scheme, are reported.

This edition is complemented by an article reporting on the DIA/TOPRA workshop held in Brussels on the status of the EU Falsified Medicines Directive. Some of the important challenges to fully implementing the safety features for the Directive in 2019 are noted by speakers from European health agencies and the European Commission. This article includes a brief follow-up quiz to consolidate your learning, and allows you to claim one lifelong learning (LLL) hour in your continuing professional development (CPD) record. If you are a TOPRA member, you can record this on our website under the “My TOPRA” tab.