Safety reporting continuity to protect patient safety and maintain compliance

Minimising risk during the global COVID-19 pandemic

Scientists are working diligently to learn more about the Coronavirus and health boards are changing guidance to adapt to this newly available information. The response to this information varies on a regional and country level as does regulatory and submission guidance.

Special considerations during the COVID-19 pandemic

In this complex evolving environment you may experience the following challenges in safety reporting;

- Accessing and analysing rapidly changing regulatory intelligence information
  - Requirements released by Competent Authorities and Ethics Committees
- Making decisions on safety reporting operations where there is lack of guidance or incomplete information from regulatory bodies
- Applying the latest regulatory information to safety reporting
  - Training staff on the implications of the latest regulatory intelligence for compliant submissions
- Changing methods of delivery for safety documents
  - Some countries have already shifted from hand-delivery or courier methods to electronic submissions with varying timelines and re-submission requirements
- Potentially reduced drug safety specialist workforce due to illness or infrastructure limitations

Regulatory intelligence and automated solution to maintain compliance

ICON's Safety Reporting Solution combines pharmacovigilance expertise, regulatory intelligence and innovative technology to protect patient safety and maintain compliance.

- Regulatory Intelligence is pre-programmed into the system for over 80 countries and is kept up to date on a real time basis by a dedicated safety intelligence team
- A validated 21 CFR part 11 compliant system uses rules and automated decision-making to execute safety packages to appropriate stakeholders in a timely and efficient manner.
- Simultaneous compliance tracking within the system and an integrated root cause analysis system enables robust oversight by drug safety experts. This is supplemented by compliance reporting on a monthly basis.
- Safety specialists distributed across the globe support business continuity by configuring the system with study-specific information 22 hours a day

The solution can be deployed easily and rapidly on studies and does not require integration with the safety database.

Case Study:

Being proactive to ensure operational continuity during the COVID-19 pandemic

The Challenge

The safety reporting team recognised that due to restricted travel and country specific lockdowns during the COVID-19 outbreak, there was a potential risk of delays in submission packages because of the required delivery methods of some Competent Authorities and Ethics Committees. By interrogating multiple regulatory intelligence sources, 127 incidences were identified where hand or courier delivery was required for safety submissions across the globe. The team proactively contacted authorities for advice on alternative submission methods.

Within ten days of direct contact with the Competent Authorities and Ethics Committees the required submission methods were established for all regulatory safety recipients that originally required hand-delivery. The methods advised were multifaceted and some included differing start and stop date instructions;

- Use of email and no re-submission, alternative method to be used indefinitely
- Use of email and no re-submission, to revert to hand delivery or courier after 'X' date in pandemic
- Use of email then re-submission, to revert to hand delivery or courier after 'Y' date in pandemic
- Delivery by dedicated courier or hand delivery on 'Z' days of the week
- Delivery by dedicated courier or hand delivery at 'A' timeslots

The Solution

ICON's Safety Reporting Solution combines pharmacovigilance and regulatory expertise with innovative automation in a validated platform. A cloud-based system featuring automated and configurable business rules provides prioritisation, oversight and correct package preparation detail. All newly available information was converted into reporting rules and programmed into the Safety Reporting system by the regulatory intelligence team to support correct automated submission. This approach reduced the risk of human error which could have been an issue due to multiple dimensional instructions. Minimal staff training was required due to process automation.

The Outcome

The solution successfully delivered 100% compliance with safety submissions despite the volume and complexity of the change. At this time 12% of regulatory safety recipients contacted have changed their submission process indefinitely to electronic methods due to the proactive contact.

Contact us to find out how our Pharmacovigilance solutions can keep patients safe and your study on track.

ICONplc.com/Contact

For more information on the Safety Reporting Solution please read Whitepaper

For more information or other services that can help you overcome operational challenges visit:

ICONplc.com/covid-19