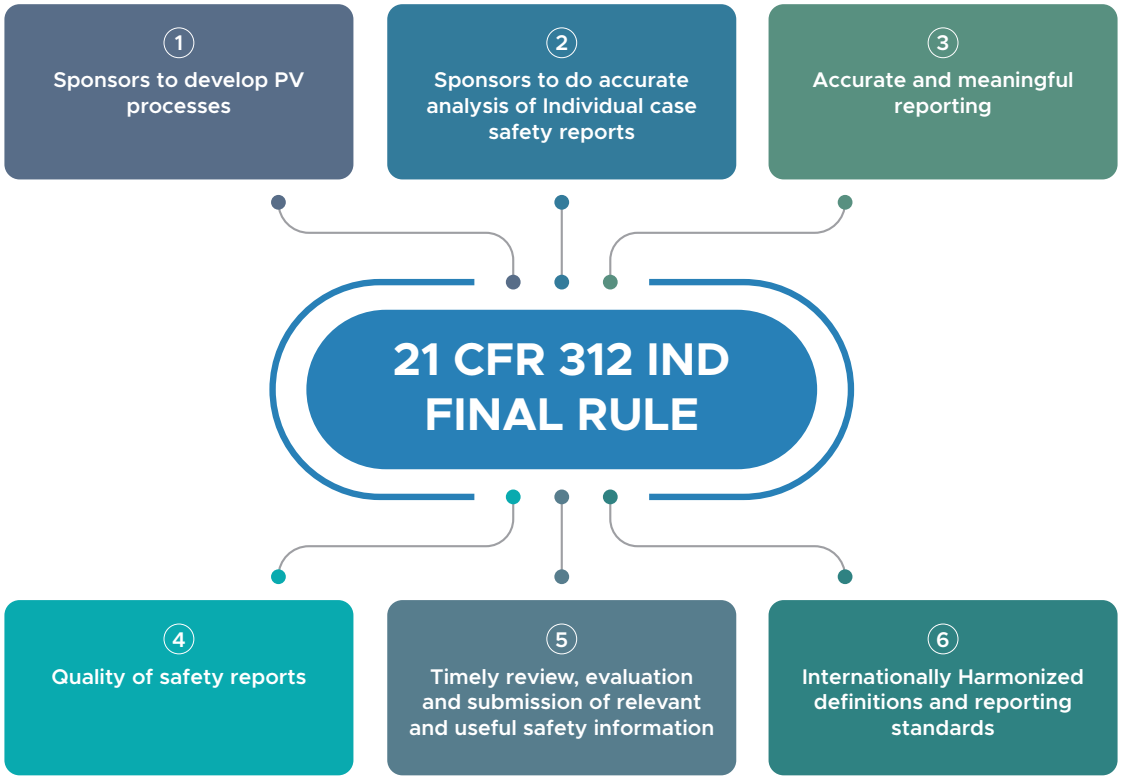
A QUALITY FOCUSED & COST-EFFECTIVE PHARMACOVIGILANCE MODEL

iQure CLINICAL

Global Pharmacovigilance Consulting and Drug & Device Safety Services

BACKGROUND

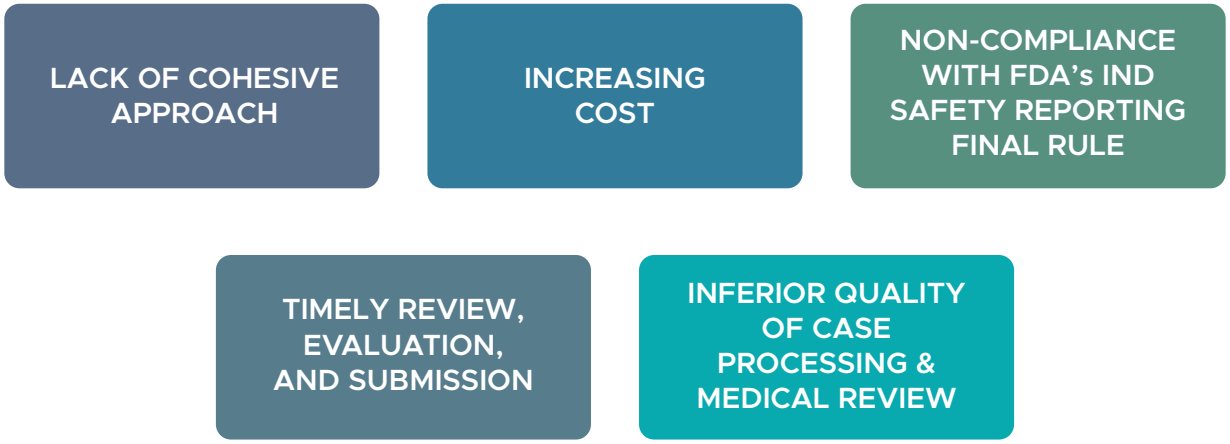
The IND safety reporting final rule outlines FDA's expectations from the sponsors to take initiative in developing well defined processes for timely and accurate analysis of individual case safety reports and aggregate data for clinically meaningful reporting to the FDA during clinical development.



"The new IND requirements facilitate expediting FDA's review of critical safety information ensuring better protection of human subjects enrolled in clinical trials."

CHALLENGES

- Sponsor companies are relying on an outsourced model for cost-effective approach, however, ending up compromising on the quality of data.
- Overseas outsourcing model has led to lack of cohesive approach between Sponsors and the CROs for timely review, evaluation and submission of relevant safety information.
- In the in-house model, sponsor has the entire cost burden of developing pharmacovigilance system



IQURE SOLUTION

"Committed Towards Cost Effective & Quality Safety Solutions"

IQURE MODEL

At iQure, our pharmacovigilance experts are part of the core clinical development team. This allows sponsors to make early decisions related to safety, when compared to an outsourced model. iQure provides US based robust pharmacovigilance program which is quality oriented, cost-effective and scalable, ensuring prompt identification and timely analysis of safety issues and risks.

US BASED HIGH QUALITY PHARMACOVIGILANCE EXPERTS

01

1) Pharmacovigilance Consulting

2) Process Development

MEMBER OF THE CORE CLINICAL DEVELOPMENT TEAM

02

1) Accurate and timely analysis of safety issues

2) Identifying early risks for developmental compounds

3) Meaningful reporting to the FDA and regulatory compliance

4) Higher chances of NDA success

5) End to end pharmacovigilance training programs

COST ADVANTAGE AND SCALABILITY

03

1) Cost effective when compared to in-house and outsourced model

2) Wide spectrum of pharmacovigilance expertise under one roof

IQURE ADVANTAGES:

At iQure, we specialize in safety monitoring and implementing pharmacovigilance systems during clinical development and post marketing surveillance. With our accessibility to resources and supported by our subject matter experts, we promise to deliver high quality output within the stipulated timelines.

01 Deeper understanding of Drug Development Processes

02 iQure experts will be part of the core clinical development team

03 Accessibility to resources as per sponsor requisite

04 Uninterrupted support from our experts located onsite and at our US based office

05 Accurate and timely analysis of safety issues

06 Identifying early risks related to developmental compounds

07 Meaningful reporting to the FDA

08 Regulatory compliance

09 Experts available for filing NDA and building SOPs on signal detection, risk assessments & management

10 Providing complete training on every aspect of Pharmacovigilance

TEAM

Comprises of US based pharmacovigilance physicians, pharmacists and healthcare professionals.

TEAM EXPERTISE: WE SPECIALIZE

We specialize in developing processes related to safety monitoring during clinical development and post marketing surveillance. With our experts you are guaranteed to receive high quality safety data with high chances for a successful NDA approval.

- High quality Medical Review
- Aggregate reports (PBRER/PADER/DSUR)
- Developing SOPs
- Risk evaluation and mitigation

SERVICES

At iQure, we provide a wide spectrum of services from Safety database hosting to case management that are all easy to implement and compliant as per ICH, GCP and other regulatory checkpoints.

- Safety database hosting via Oracle Argus
- Case Management
- Signal detection/management and Risk Evaluation & Mitigation Strategies (REMS)
- Support NDA filing
- Literature surveillance services
- Pharmacovigilance procedures
- Preparation of Interim safety reports (on demand)
- Preparation of aggregate reports (PBRER, PADER, DSUR & PSUR)
- End to end pharmacovigilance Training
- Medical information Contact Centre for handling medical inquires

ADVANTAGES FOR THE SPONSORS

At iQure, our professionals are driven and committed to provide quality oriented solutions with zero tolerance policy on non-conformities.

01 Pharmacovigilance experts for clinical development and post-marketing surveillance	02 Accurate analysis of safety concerns	03 Pharmacovigilance training	04 Medical information contact centre
05 Assurance of regulatory compliances	06 Increased efficiency gains and effective utilization of resources	07 Cost savings	08 Data integrity

iQure offers solutions for better and safer drugs & devices. iQure is committed to provide unmatched, comprehensive and cost effective pharmacovigilance solutions by partnering with pharmaceutical companies / Sponsors and CROs.

Learn more about iQure Clinical's cost effective Pharmacovigilance model by visiting our website: www.iqureclinical.com

44 Bearfoot Rd Suite 200,
Northborough, MA 01532
Phone: (508) 281 9620
Email: info@iqureclinical.com