ICSR Form

Individual Case Safety Report					
General Information					
ICSR Number		**ICSR Status**	☐ Initial Version	☐ Follow-Up Version	
First Receipt Date		**LSR Receipt Date**			
Reporter Type	☐ Authority	☐ Healthcare Provider	☐ Consumer	☐ RDS Employee	
Reporter Initials		**Can Reporter be contacted for follow-up?** ☐ Yes	☐ No		
Reporter Email		**Reporter Phone No.:**			
Case Seriousness	☐ Non-Serious	☐ Serious	☐ Life-Threatening		
Other Case Numbers (please specify, i.e. Complaint, Regulatory, Partner…etc.)					
Patient Information					
Patient Initials	**Age**	**Gender**	**Follow- Up Requested (Yes / No)**		

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Reaction/ Event							
Adverse Event		**Duration**		**Outcome**		**Seriousness**	
Drug Information (exclude those to treat adverse events)							
Drug Trade Name and Generic Name	**Indication**	**Dose and Dosage Form**	**Route of Administration and Frequency**	**Action Taken**	**Start Date**	**Stop Date**	**Ongoing (Yes/ No)**
Action taken regarding the suspect product	☐ No change ☐ Dose Reduced ☐ Dose Increased ☐ Withdrawn ☐ Unknown						
Did reaction abate after stopping drug?	☐ Yes ☐ No ☐ NA			**Did reaction reappear after drug reintroduction?**		☐ Yes ☐ No ☐ NA	

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Relevant Medical History/ Past Drug Therapy/ Procedures				
Description of Condition	**Start Date**	**Stop Date**	**Results/ Comments**	**Ongoing (Yes / No)**

Laboratory Tests including Vital Signs				
Test Name	**Result (with Units)**	**Reference Range (High/ Low)**	**Test Date**	**Comments**