Global: Erivedge EU Pregnancy Report Form

FOR ROCHE USE ONLY		
Roche Received Date (dd-MMM-yyyy):	Local No:	AER No:
Report Type:	Prospective ☐	Retrospective ☐

1. REPORTER INFORMATION

Note: If available please provide reporter's occupation. If data privacy allows please provide name, address and/or phone number.

Reporter Name: Initial ☐ Follow-up ☐

Type: ☐ Physician (Specialty) ☐ Pharmacist

☐ Consumer ☐ Other (Specify)

Contact Address: Telephone Number:

Fax Number:

Postal/Zip Code: E-mail:

2. EXPOSED PARENT'S DETAILS

Note: If data privacy allows please provide at least one descriptor. Please ensure patient's age or age group is captured whereever possible.

Who was exposed: Father ☐ Mother ☐ Initials: Date of Birth: dd MMM yyyy

Height: inch ☐ cm ☐ Age at Conception:

Weight: lb ☐ kg ☐ Postal Code (France only):

Ethnic origin: Black ☐ Caucasian ☐ Hispanic ☐ Asian ☐ Other ☐ (Specify):

3. PRODUCT INFORMATION

(Enter all relevant medications taken before (up to 24 months for Erivedge female treated patients), and during pregnancy or if the father exposed enter medications taken prior to conception or up to 2 months after the last dose of Erivedge).If more than 5, continue in Additional Relevant Information, Section 11

	Product Name (Generic/Trade)	**Suspect**	**Lot/ Batch #**	**Time of Exposure** (× as applicable)					**Route**	**Strength and Formulation** (mg, cap, tab)
				Pre conception	Trimester 1	Trimester 2	Trimester 3	Delivery		
1.		☐		☐	☐	☐	☐	☐		
2.		☐		☐	☐	☐	☐	☐		
3.		☐		☐	☐	☐	☐	☐		
4.		☐		☐	☐	☐	☐	☐		
5.		☐		☐	☐	☐	☐	☐		

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	Dosage Regimen	Start Date (dd-MMM-yyyy)	Stop Date (dd-MMM-yyyy)	Ongoing	Indication for Use
1.				☐	
2.				☐	
3.				☐	
4.				☐	
5.				☐	

4. PREGNANCY INFORMATION

LMP Date Last menstrual period: dd MMM yyyy Est ☐

Estimated Date of Delivery: dd MMM yyyy

Conception Date: dd MMM yyyy Est ☐

5. MEDICAL HISTORY

Contraception (may choose more than one)

None	☐	Condom	☐
Contraceptive Medication	☐	Surgical Sterilization (Male)	☐
Diaphragm	☐	Surgical Sterilization (Female)	☐
IUD	☐	Withdrawal	☐
Infertility (Male)	☐	Rhythm	☐
Infertility (Female)	☐	Unknown	☐
Spermicide	☐		

Number of previous

Pregnancies	
Therapeutic Abortions	
Spontaneous Abortions	
Stillbirth	
Deliveries	
Babies born with defects	

Risk Factors/ Medical History

Unknown	☐
Alcohol	☐
Allergies*	☐
Diabetes*	☐
Infection*	☐
Smoking	☐
Drug abuse	☐

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Other/Relevant History **(*specify below)** ☐

Details: (include dates & outcome as applicable) _____

6. PREGNANCY OUTCOME

Ongoing	☐	Ectopic pregnancy	☐	Spontaneous abortion	☐	Unknown	☐
Live birth	☐	Stillbirth	☐	Therapeutic abortion	☐	Lost to follow-up	☐

Provide date if applicable: ____ ____ ____ (dd MMM yyyy)

7. RELEVANT LABORATORY TESTS/PROCEDURES PRE AND POST OUTCOME (e.g. Amniocentesis, ultrasound)

	Tests	**Results** Units and normal values if applicable	**Pending**	**Pre/Post Outcome?**	**Date** dd-MMM-yyyy
1.			☐	Pre ☐ Post ☐	
2.			☐	Pre ☐ Post ☐	
3.			☐	Pre ☐ Post ☐	

Further details: _____

8. BIRTH OUTCOME

Infant/Fetal Outcome:

Number of infants/fetuses ____ (in the event of more than 1 infant/fetus, complete Infant Information sections 8-11 on a separate form)

Normal ☐

Abnormal (birth defects/congenital abnormalities and other events experienced by the fetus/baby) ☐ Specify _____

Unknown ☐

Death ☐ Date: ____ ____ ____ (dd MMM yyyy) Cause of death: _____

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Autopsy results:		

9. INFANT INFORMATION

Gender:	Weight:		Length:		Head circumference:	
Male: ☐		lb ☐		inch ☐		inch ☐
Female: ☐		kg ☐		cm ☐		cm ☐

Gestational Age at Delivery/Abortion ☐☐ (weeks)

Apgar Scores 1 minute ☐☐ 5 minutes ☐☐ 10 minutes ☐☐

Were there any unusual features about the pregnancy or its outcome?

Yes ☐ No ☐

If yes, specify _____

_____

Follow-up examination of the child:

Date: ☐☐ dd ☐☐☐ MMM ☐☐☐☐ yyyy

Findings: _____

_____

Paediatrician (in case of referral); Name: _____

Address: _____ Telephone No: _____

Fax No: _____

E-mail:

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10. RELEVANT LABORATORY TESTS/PROCEDURES FOR BABY/FETUS

	Tests	**Results** (unit and normal values if applicable)	**Pending**	**Date** dd-MMM-yyyy
1.				
2.				
3.				
4.				

11. ADDITIONAL INFORMATION Continue on Optional Supplementary Form if necessary

Reporter Signature: **Date** (dd-MMM-yyyy):

Contact name for further information on pregnancy: (if different from REPORTER)

Contact Address: _____ Telephone No: _____

_____ Fax No: _____

_____ Email: _____

If completed by Roche delegate, ensure the data completed reflects the reporter's opinion

FOR ROCHE USE ONLY **Signature:** _____ **Date** (dd-MMM-yyyy): _____

PRINT NAME:

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ADDITIONAL INFORMATION (Optional):

Name: **Signature:**

Date (dd-MMM-yyyy):

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