Applicability (max. displayed 12)

clinical gred
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clinical dev operations
clinical dev pv
clinical dev science
clinical global_product_strategy
clinical local operations
clinical local pv
clinical local ma

Site(s) where applicable (max. displayed 6)

Global

Author(s) (max. displayed 3)

Beatriz Bustillo

Electronic Signatures (max. displayed 10)

Signed by	Meaning of Signature	Date (dd-MMM-yyyy HH:mm:ss Basel Server Time)
Tomita Kristen	Quality Approval	26-Jan-2018 15:53:47 CET
Diedrick Maria	Document Approval	29-Jan-2018 18:41:59 CET

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N/A

Reference Numbers(s) of Governing Documents (max. displayed 10)

Reference Numbers(s) of Attached Documents (max. displayed 35)

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Global: Pregnancy Reporting Form

Instructions:

This form is to be used for reporting pregnancy information and any Adverse Events (AEs) and Special Situations associated with the fetus/infant originating from a spontaneous source, a Non-Interventional Study (NIS), a Market Research and Patient Support Program (MAP), a Pre-Approval Access (PAA) / Compassionate Use (CU) Program and a Post-Trial Access Program (PTAP).

For pregnancies, AEs and Special Situations originating from

- Spontaneous sources: Omit section A, B, C and D and start to complete the form with Section 1 – Reporter Details.
- NIS: Complete section A first in addition to the other sections.
- MAP: Complete section B first in addition to the other sections.
- PAA/CU Program: Complete section C first in addition to the other sections.
- PTAP: Complete section D first in addition to the other sections.

For EU Isotretinoin (Roaccutane) pregnancies and all Mycophenolate Mofetil (Cellcept) pregnancies, complete additional supplementary forms at the end.

If the mother/father has experienced an AE/Special Situation, this should be reported using *Global: Adverse Event and Special Situation Reporting Form (SRD-0120176).*

The four essential elements for reporting pregnancy information are marked with * of which at least one subfield needs to be populated in each section.

Once completed, forward the form to your Roche Local Safety Unit (LSU) or to Roche Safety Operations as applicable.

For dates, spell out the first three letters of the month, DD/MMM/YYYY, e.g., 07/APR/2015.

Note: The format/wording of this form may be modified by the Roche LSU as needed as long as the requirements on essential data that needs to be collected is not omitted.

A. Non-Interventional Study (NIS) REPORTS ONLY

NIS Protocol Number:	
Site Number:	
Patient Number:	

Did the patient receive a studied medicinal product as per the NIS protocol? ☐ Yes ☐ No

Are any of the adverse events reported on this form exempted from collection as per the NIS protocol? ☐ Yes ☐ No

B. Market Research and Patient Support Program (MAP) REPORTS ONLY

Note: Even if there is no identifiable patient, complete as many details as possible.

MAP Identifier:		Project Title:	
MAP Service Provider:		Respondent ID:	
Address:		E-mail Address:	
		Telephone Number:	
Country:		Fax Number:	

C. Pre-Approval Access (PAA)/Compassionate Use (CU) Program REPORTS ONLY

Program Number:	
Patient Identifier:	

D. Post-Trial Access Program (PTAP) REPORTS ONLY

Program Number:	
Patient Identifier:	

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

Reporter First Name:		Occupation:
Reporter Surname:		☐ Physician (specify specialty):
Address:		☐ Pharmacist
Postal/Zip Code:		☐ Nurse
Country:		☐ Consumer/Patient
E-mail Address:		☐ Legal

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Telephone Number:		☐ Company Representative
Fax Number:		☐ Other (specify):

2. PERMISSION TO CONTACT HEALTHCARE PROFESSIONAL (HCP)

If the reporter is a consumer/patient, permission to contact HCP regarding pregnancy/adverse event(s)? ☐ Yes ☐ No	HCP Contact Details:

3. PARENT'S DETAILS * *Note: If data privacy allows please provide at least one descriptor. Please ensure the patient's age or age group is captured wherever possible.*

Exposed Parent: ☐ Mother ☐ Father

Mother

Name/Initials:		Date of Birth:		Age at conception:	Years
Weight:	☐ kg ☐ lb				
Height:	☐ cm ☐ inch				
Ethnic Origin:	☐ Asian ☐ Black ☐ Caucasian ☐ Hispanic ☐ Other (specify):				

Father (if exposed)

Name/Initials:		Date of Birth:		Age at conception:	Years
Weight:	☐ kg ☐ lb				
Height	☐ cm ☐ inch				
Ethnic Origin:	☐ Asian ☐ Black ☐ Caucasian ☐ Hispanic ☐ Other (specify):				

4. PRODUCT INFORMATION * *- If more than 5, continue in Additional Relevant Information, Section 14.*

For maternal exposure, enter all medications taken before and during pregnancy or breastfeeding.
For paternal exposure, enter medication taken prior to conception only.

	Product Name (report brand name if available)	Indication	Start Date	Stop Date	Ongoing? (Y/N/Unknown)	Suspect (Y/N)
1						
2						
3						
4						
5						

	Time of Exposure (× as applicable)						Route	Dose and Unit	Strength and Formulation	Batch/Lot Number
	Preconception	Trimester 1	Trimester 2	Trimester 3	Delivery	Breast feeding				
1	☐	☐	☐	☐	☐	☐				
2	☐	☐	☐	☐	☐	☐				
3	☐	☐	☐	☐	☐	☐				
4	☐	☐	☐	☐	☐	☐				
5	☐	☐	☐	☐	☐	☐				

5. MEDICAL HISTORY OF MOTHER AND FATHER

Risk Factors/Medical History – MOTHER	Risk Factors/Medical History – FATHER
☐ Unknown	☐ Unknown
☐ Alcohol	☐ Alcohol
☐ Allergies	☐ Allergies
☐ Diabetes	☐ Diabetes
☐ Infection	☐ Infection
☐ Smoking	☐ Smoking
☐ Drug abuse	☐ Drug abuse
☐ Other (specify):	☐ Other (specify):

6. CONTRACEPTION - *May choose more than one .*

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

7. PREVIOUS OBSTETRIC HISTORY *- If more than 6 pregnancies , continue in Additional Relevant Information, Section 14.*

Use keys below

Pregnancy #	**1**	**2**	**3**	**4**	**5**	**6**
Pregnancy Outcome: A. Therapeutic abortion B. Spontaneous abortion C. Stillbirth D. Ectopic E. Live birth (pre-term) F. Live birth (full-term) G. Unknown						
Infant/Fetal Outcome: 1. Unknown 2. Normal 3. Abnormal, specify: 4. Death, specify if intrauterine death, stillbirth or neonatal death:						

8. CURRENT PREGNANCY INFORMATION

LMP Date:	☐ Estimated
Conception Date:	☐ Estimated
Estimated Date of Delivery:	

9. RELEVANT LABORATORY TESTS/PROCEDURES CARRIED OUT ON THE MOTHER

Enter what tests were performed, e.g., ultrasound, amniocentesis; name and results of each one, plus units and normal ranges if applicable. If additional space is required, continue in Section 14.

Test	**Date of Test**	**Result**	**Pending?**	**Pre/post outcome**
			☐	
			☐	
			☐	
			☐	
			☐	

10. PREGNANCY/BIRTH OUTCOME *

☐ Unknown

Date of last information on pregnancy: Gestation week:

Pregnancy interrupted ☐ Spontaneous abortion ☐ Therapeutic abortion ☐ Ectopic ☐ Stillbirth	Date: Gestation week:	**Pregnancy not interrupted** ☐ Live birth ☐ Ongoing	Date: Gestation week:
Vaginal delivery ☐ Term ☐ Pre-term ☐ Forceps/Vacuum (instrumental)	Date: Gestation week:	**Caesarean** ☐ Scheduled ☐ Emergency	Date: Gestation week:

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11. INFANT/FETAL OUTCOME - *For multiple infants, complete one form per infant.*

Number of infants:
☐ Unknown
☐ Normal
☐ Abnormal
Abnormalities of fetus/infant, i.e., structural malformation, growth alteration, functional deficit, specify:
☐ Death, specify if intrauterine death, stillbirth or neonatal death:
Date of death:
Cause of death:
Autopsy result:

12. INFANT INFORMATION - *For multiple infants, complete one form per infant.*

Gender: ☐ Female ☐ Male

Weight: Units:

Length: Units:

Head circumference: Units:

Gestational age at delivery/abortion: Weeks

Apgar Scores: 1 Minute 5 Minutes 10 Minutes

Were there any unusual features about the pregnancy and its outcome? ☐ Yes ☐ No
If yes, specify:

Follow-up examination of the infant findings:
Date:

13. RELEVANT LABORATORY TESTS/PROCEDURES FOR FETUS/INFANT

Such as ultrasonography, amniocentesis, Chorionic Villus Sampling (CVS)

Test	Date	Result	Normal Y/N	Result Pending?	Pre/post outcome
				☐	
				☐	
				☐	

14. ADDITIONAL RELEVANT INFORMATION

Additional obstetrical history, pregnancy course (including investigations e.g., pregnancy test, ultrasound, amniocentesis, complications, adverse events, etc.) and additional relevant medical history.

15. PEDIATRICIAN (IN CASE OF REFERRAL)

Name:			
Address:		E-mail Address:	
		Telephone Number:	
		Fax Number:	

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LRN: AER: Local Received Date: Company Received Date:

Report Type ☐ Initial ☐ Follow-Up
☐ Prospective ☐ Retrospective
☐ Spontaneous ☐ Literature ☐ Other (specify):
NIS Protocol Number: MAP ID: PAA/CU Program Number:
PTAP Program Number:

Ancillary Documentation? ☐ Yes ☐ No
Supplementary Form attached? ☐ Yes ☐ No

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Global: Pregnancy Reporting Form

EU ISOTRETINOIN (Roaccutane) PREGNANCY SUPPLEMENTARY FORM

PREVIOUS ACNE TREATMENT

	Product Name (report brand name if available)	Batch/Lot Number	Manufacturer	Start Date	Stop Date	Route	Strength, Form and Dose
1							
2							
3							
4							
5							

PREGNANCY PREVENTION CHECKLIST

1. Counselling regarding the risks of pregnancy during Roaccutane therapy and contraceptive methods was completed prior to starting Roaccutane?
   ☐ Done
   Done by:
   ☐ Not done
2. Was the patient on contraception at start of Roaccutane therapy?
   ☐ Yes ☐ No
3. Baseline pregnancy test to qualify for Roaccutane therapy?
   ☐ Yes ☐ No
   Type: Date:
4. Was monthly follow-up performed?
   ☐ Yes ☐ No ☐ N/A
5. Was monthly follow-up pregnancy test completed?
   ☐ Yes ☐ No ☐ N/A
   Most recent test:
   Type: Date: Result:
6. Was a pregnancy test done 5 weeks after stopping Roaccutane therapy?
   ☐ Yes ☐ No ☐ N/A
   Type: Date: Result:
7. Was the patient verbally warned about pregnancy risks?
   ☐ Yes ☐ No
8. Did the patient sign an acknowledgement form?
   ☐ Yes ☐ No ☐ N/A
   Date:
9. Was the patient given a Patient Brochure on Contraception?
   ☐ Yes ☐ No
10. Was the patient given a Patient Information Brochure?
    ☐ Yes ☐ No
11. Were other written materials given to the patient?
    ☐ Yes ☐ No
    Specify:
12. Was the prescription for Roaccutane therapy handled as per dispensing limitations?
    ☐ Yes ☐ No
    30 day supply? ☐ Yes ☐ No
    7 day prescription validity? ☐ Yes ☐ No
13. Were the patient's chosen contraceptive methods discussed with the prescriber?
    ☐ Yes ☐ No
14. Did the patient verbalize an understanding of pregnancy risks and contraceptive methods presented to her?
    ☐ Yes ☐ No
15. Was the patient on contraception one month after discontinuing Roaccutane therapy?
    ☐ Yes ☐ No

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Global: Pregnancy Reporting Form

MYCOPHENOLATE MOFETIL (Cellcept) PREGNANCY SUPPLEMENTARY FORM

CONTRACEPTION AND PREGNANCY TESTING
Number of negative pregnancy tests obtained prior to start of Cellcept treatment: ☐ One ☐ Two ☐ None
Date of negative pregnancy tests: 1) 2)
Were repeated pregnancy tests performed during routine follow-up visits: ☐ No Yes ☐ If yes specify frequency:
Was the patient on contraception at start of Cellcept therapy? ☐ Yes ☐ No If yes, ensure section 5 – Medical History of Mother is completed
Was the patient on contraception throughout Cellcept therapy? ☐ Yes ☐ No Any change in method?
Were two forms of contraception used simultaneously during and after discontinuing Cellcept therapy? ☐ Yes ☐ No Specify details:
Was the patient on contraception a) 6 weeks after discontinuing Cellcept therapy in maternally exposed pregnancies? ☐ Yes ☐ No b) 90 days after discontinuing Cellcept therapy in paternally exposed pregnancies (applicable for both mother and father)? ☐ Yes ☐ No Any change in method?
Provide details of contraceptive failure during/after Cellcept therapy:

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Global: Pregnancy Reporting Form

ALECTINIB (Alecensa) PREGNANCY SUPPLEMENTARY FORM

PREVIOUS and CONCOMITANT TREATMENT of the PARENT

	Product Name (report brand name if available)	Batch/Lot Number	Manufacturer	Start Date	Stop Date	Route	Strength, Form and Dose
1							
2							
3							
4							
5							

CONCURRENT DISEASE of the PARENT

1	
2	
3	
4	
5	

Details to Question 9
Test during pregnancy - Mother

	Relevant blood test

Biochemistry

Test	Date of Test	Result
1		
2		
3		
4		
5		

Hormones

Test	Date of Test	Result
1		
2		
3		
4		
5		

Other (please specify)

Test	Date of Test	Result
1		
2		
3		
4		
5		

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	Urinanalyses	
☐	Yes	☐ normal (please provide test date) ☐ abnormal (please provide test date)
☐	No	

Details to question 11
INFANT/FETAL OUTCOME

Birth defect diagnosed by specialist	**If yes, specify specialty** *(by code #)* *1. Cardiologist* *2. Dysmorphologist/ Teratologist* *3. Family Medicine* *4 Maternal Fetal Medicine* *5 Midwife* *6 Neonatalogist* *7 Ob/Gyn* *8 Pediatrician* *9 Radiologist* *10 Other, specify*	**Form Completed by**	**Date Completed** (*dd mmm yyyy*)
☐ Yes	☐ No		

	Birth defect *(list birth defect)*	**Was the defect attributed to Alecensa therapy?** *1 = yes* *2 = no* *3 = unknown*	**Other factors that may have contributed to this outcome** *1 = unknown* *2 = other, specify*	**Age** *(in months, when defect was noted)*
1				
2				
3				
4				
5				

Details to question 13
Prenatal test - Fetus

Ultrasonography	**Date of Test**	**Result**
Amniocentesis	**Date of Test**	**Result**
Chorionic Villus Sampling	**Date of Test**	**Result**
Other, please specify	**Date of Test**	**Result**

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Contact Details Pediatrician
Name
Specialty
Address
Phone
Fax
Email
Alternate Contact
Provider’s Signature
Date

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