

**EUROPEAN REGISTRY OF SEVERE CUTANEOUS ADVERSE
REACTIONS TO DRUGS AND COLLECTION OF
BIOLOGICAL SAMPLES**

RegiS CAR

Case Record Form

Interview no.

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AGEP

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Dokumentationszentrum schwerer Hautreaktionen (dZh)
Universitäts-Hautklinik
Hauptstr. 7
D-79104 Freiburg
Tel. 0761 270-6723

EUROPEAN REGISTRY OF SEVERE CUTANEOUS ADVERSE REACTIONS TO DRUGS AND COLLECTION OF BIOLOGICAL SAMPLES

RegiS CAR

Interview no.

PATIENT'S DATA

Initials of the patient

date of birth

Age

country of birth

Gender

male

female

Death before interview

no

yes

Participation
agreed to by the patient

registry

cohort study

genetic study

Interview no.

HOSPITAL DATA

Reporting hospital / department

hospital no.

date of admission

Treating hospital / department

hospital no.

date of admission

Date of notification

date of interview

Transfer from one or more hospitals to the reporting / treating hospital:

- no
- yes
- unknown

If yes, first hospital:

hospital no.

date of admission

Retrospective assessment

- no
- yes

Development of skin reaction

- prior to admission
- during inhospital stay

DIAGNOSES AND CLINICAL COURSE

Admission diagnoses

1) _____

2) _____

3) _____

Date

Clinical symptoms

Fever

no

yes

unknown

If yes,

date of onset

date of normalization*

highest temperature (°C)

* if cured before admission

Interview no.

FOR CASES OF AGE P ONLY

SKIN SYMPTOMS

Subjective symptoms

	no	yes	unknown	date of onset	date of resolution*
Burning, pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

Pruritus	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
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Erythema, exanthema	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
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If yes,

- diffuse erythema

- urticarial

- maculopapular

- purpura

- target lesions

- other:

(please specify)

localization of exanthema:

mainly folds

widespread

face

other:

(please specify)

Maximum extent of exanthema

(percentage related to the BSA)

	no	yes	unknown	date of onset	date of resolution*
Facial edema	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

* if cured before interview

Interview no.

FOR CASES OF AGEP ONLY

MUCOSAL EROSIONS

	no	yes	unknown	date of onset	date of resolution*
Lips	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Mouth	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Eyes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Genital	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Anal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Nasal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

LABORATORY FINDINGS

- Leucocytes

On admission: _____ / μ l not done

Maximum: _____ / μ l date of maximum

- Neutrophils

On admission: _____ / μ l

Maximum: _____ / μ l

- Eosinophils

On admission: _____ / μ l

Maximum: _____ / μ l

*if cured before interview

FOR ALL CASES

FURTHER INFORMATION FOR CASE VALIDATION

	no	yes	unknown	date of first occurrence
Photographs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Biopsy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Diagnosis by a dermatologist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

If yes, please specify: _____

Further photographs:

Date	Notes
_____	_____
_____	_____
_____	_____

SCORTEN-PARAMETERS (within 3 days after admission)

	no	yes	not done
- Urea > 10 mmol/l	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If yes, highest value: _____ mmol/l			
- Glycemia > 14 mmol/l	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If yes, highest value: _____ mmol/l			
- Bicarbonate < 20 mmol/l	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If yes, lowest value: _____ mmol/l			
- Heart rate > 120 /min	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Interview no.

SYMPTOMS / EVENTS WITHIN 1 MONTH BEFORE THE RECENT SKIN REACTION

Herpes labialis or fever blisters no yes unknown date of onset date of normalization*

Do you have recurrent herpes labialis or fever blisters?

no yes unknown date of last eruption

Herpes genitalis no yes unknown date of onset date of normalization*

Do you have recurrent genital herpes?

no yes unknown date of last eruption

*if cured before admission

SYMPTOMS / EVENTS WITHIN 1 MONTH BEFORE THE RECENT SKIN REACTION

	no	yes	unknown		
Infections	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
If yes,				date of onset	date of normalization*
- influenza / influenza-like illness		<input type="checkbox"/>		<input type="text"/>	<input type="text"/>
- rhinopharyngitis / common cold		<input type="checkbox"/>		<input type="text"/>	<input type="text"/>
- tonsillitis		<input type="checkbox"/>		<input type="text"/>	<input type="text"/>
- sinusitis		<input type="checkbox"/>		<input type="text"/>	<input type="text"/>
- acute otitis		<input type="checkbox"/>		<input type="text"/>	<input type="text"/>
- acute bronchitis		<input type="checkbox"/>		<input type="text"/>	<input type="text"/>
- pneumonia		<input type="checkbox"/>		<input type="text"/>	<input type="text"/>
- acute gastroenteritis		<input type="checkbox"/>		<input type="text"/>	<input type="text"/>
- acute cystitis		<input type="checkbox"/>		<input type="text"/>	<input type="text"/>
* bacterial infection proven		<input type="checkbox"/>			
* prior cystitis		<input type="checkbox"/>			
- other infections		<input type="checkbox"/>			
_____				<input type="text"/>	<input type="text"/>
(please specify)					
_____				<input type="text"/>	<input type="text"/>
(please specify)					

HIV-status

	no	yes	unknown
HIV	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
AIDS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If yes,
most recent CD4 count per µl:

*if cured before admission

Interview no.

HAVE YOU IN THE PAST HAD ANY OF THE FOLLOWING DISEASES?

	no	yes	unknown	year of event
- Atopic dermatitis / childhood eczema	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
- Psoriasis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
- SCAR	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>

If yes, please specify: _____

	no	yes	unknown	
Severe liver disorders?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
If yes,				<input type="text"/>

(please specify)				

	no	yes	unknown	
Severe kidney disorders?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
If yes,				<input type="text"/>

(please specify)				

	no	yes	unknown	
Rheumatic / autoimmune diseases?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
If yes,				
- rheumatoid polyarthritis		<input type="checkbox"/>		<input type="text"/>
- systemic lupus erythematosus		<input type="checkbox"/>		<input type="text"/>
- other:		<input type="checkbox"/>		<input type="text"/>
If yes,				

(please specify)				

Interview no.

Other diseases

	no	yes	unknown	year of event
- Diabetes mellitus	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>
- Convulsive disorder / epilepsy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>
- Allergic rhinitis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>
- Asthma	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>
- Inflammatory bowel disease	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>
* Colitis ulcerosa		<input type="checkbox"/>		<input type="text"/> <input type="text"/>
* Crohn's disease		<input type="checkbox"/>		<input type="text"/> <input type="text"/>
- Malignant diseases / cancer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>

If yes, please specify: _____

Radiation therapy

	no	yes	unknown	date of most recent therapy
Have you ever had X-ray or radiation therapy? (not UV-radiation)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

If yes, for what indication?

- lymphoma

(please specify)

- brain tumor

(please specify)

- other reason:

(please specify)

medication sheet no. ___ of ___

□□□□

□□□□

MEDICATION HISTORY WITHIN 1 MONTH BEFORE HOSPITALIZATION

date of admission

□□□□□□

no drug use

□

Drug	Dose	Type of application	Begin of intake day month year	End of intake day month year	Frequency
_____		□□	□□□□□□	□□□□□□	□
Indication			□□□□□□	□□□□□□	□
_____			□□□□□□	□□□□□□	□

previous intake no yes unknown

If yes, any adverse reaction no yes unknown **If yes, please specify:**

Drug	Dose	Type of application	Begin of intake day month year	End of intake day month year	Frequency
_____		□□	□□□□□□	□□□□□□	□
Indication			□□□□□□	□□□□□□	□
_____			□□□□□□	□□□□□□	□

previous intake no yes unknown

If yes, any adverse reaction no yes unknown **If yes, please specify:**

Drug	Dose	Type of application	Begin of intake day month year	End of intake day month year	Frequency
_____		□□	□□□□□□	□□□□□□	□
Indication			□□□□□□	□□□□□□	□
_____			□□□□□□	□□□□□□	□

previous intake no yes unknown

If yes, any adverse reaction no yes unknown **If yes, please specify:**

medication sheet no. ___ of ___

MEDICATION HISTORY WITHIN 1 MONTH BEFORE HOSPITALIZATION

date of admission

no drug use

Drug	Dose	Type of application	Begin of intake day month year	End of intake day month year	Frequency
_____		<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
Indication			<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
_____			<input type="text"/>	<input type="text"/>	<input type="checkbox"/>

previous intake no yes unknown

If yes, any adverse reaction no yes unknown **If yes, please specify:**

Drug	Dose	Type of application	Begin of intake day month year	End of intake day month year	Frequency
_____		<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
Indication			<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
_____			<input type="text"/>	<input type="text"/>	<input type="checkbox"/>

previous intake no yes unknown

If yes, any adverse reaction no yes unknown **If yes, please specify:**

Drug	Dose	Type of application	Begin of intake day month year	End of intake day month year	Frequency
_____		<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
Indication			<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
_____			<input type="text"/>	<input type="text"/>	<input type="checkbox"/>

previous intake no yes unknown

If yes, any adverse reaction no yes unknown **If yes, please specify:**

medication sheet no. ___ of ___

MEDICATION HISTORY WITHIN 1 MONTH BEFORE HOSPITALIZATION

date of admission

no drug use

Drug	Dose	Type of application	Begin of intake day month year	End of intake day month year	Frequency
_____		<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
Indication			<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
_____			<input type="text"/>	<input type="text"/>	<input type="checkbox"/>

previous intake no yes unknown

If yes, any adverse reaction no yes unknown **If yes, please specify:**

Drug	Dose	Type of application	Begin of intake day month year	End of intake day month year	Frequency
_____		<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
Indication			<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
_____			<input type="text"/>	<input type="text"/>	<input type="checkbox"/>

previous intake no yes unknown

If yes, any adverse reaction no yes unknown **If yes, please specify:**

Drug	Dose	Type of application	Begin of intake day month year	End of intake day month year	Frequency
_____		<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
Indication			<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
_____			<input type="text"/>	<input type="text"/>	<input type="checkbox"/>

previous intake no yes unknown

If yes, any adverse reaction no yes unknown **If yes, please specify:**

--	--	--	--	--	--	--	--

Have you ever had an adverse reaction to drugs?

no

yes

unknown

If yes,

Drug: _____

Type of reaction: _____

Drug: _____

Type of reaction: _____

Drug: _____

Type of reaction: _____

Drug: _____

Type of reaction: _____

Drug: _____

Type of reaction: _____

DISCHARGE SHEET

Interview no.

hospital no.

Discharge diagnoses

1. _____
2. _____
3. _____
4. _____
5. _____

Results of the present admission

1. Death

date of death

2. Discharge

date of discharge

Mycoplasma infection within two months before admission

no

yes

unknown

date of diagnosis

If yes, criteria:

serology

isolation

x-ray

Interview no.

MAIN SOURCE OF INFORMATION

1) Clinical pattern of the reaction

	no	yes	unknown
* Were the skin lesions seen by the investigator in acute stage?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If not, please provide the source
(e.g., family physician, dermatologist, nurse, family member)

2) Medication history

* just patient

* just other source

If yes, please specify:

* both

If yes, please specify:

UNIT OF TREATMENT

1. Burn unit

2. Dept. of dermatology

3. Intensive care unit

4. Pediatric department

5. Internal medicine

6. Other:

(please specify)