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

R e g i S C A R

Case Record Form

Interview no. ☐☐☐ ☐☐☐☐

AGEP ☐

This is a confidential document of high importance for health research. In case of loss, if someone finds it, please send it to the following address:

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

RegiSCAR

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

☐ 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

Interview no. ☐☐☐ ☐☐☐☐

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 AGEP ONLY

SKIN SYMPTOMS

Subjective symptoms

	no	yes	unknown	date of onset	date of resolution*
Burning, pain	☐	☐	☐	☐☐☐☐☐☐	☐☐☐☐☐☐
Pruritus	☐	☐	☐	☐☐☐☐☐☐	☐☐☐☐☐☐
Erythema, exanthema	☐	☐	☐	☐☐☐☐☐☐	☐☐☐☐☐☐

If yes,

- diffuse erythema ☐
- urticarial ☐
- maculopapular ☐
- purpura ☐
- target lesions ☐
- other: _____ ☐
  (please specify)

<u>localization of exanthema</u>:

- 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	☐	☐	☐	☐☐☐☐☐☐	☐☐☐☐☐☐

* if cured before <u>interview</u>

Interview no. ☐☐☐ ☐☐☐☐

FOR CASES OF AGEP ONLY

	no	yes	unknown	date of onset	date of resolution*
Pustules	☐	☐	☐		
If yes,					
- few (< 25)		☐		☐☐☐☐☐☐	☐☐☐☐☐☐
- many (≥ 25; dozens)		☐		☐☐☐☐☐☐	☐☐☐☐☐☐
- follicular		☐		☐☐☐☐☐☐	☐☐☐☐☐☐
- non-follicular		☐		☐☐☐☐☐☐	☐☐☐☐☐☐

Localization of pustules:

- mainly folds ☐
- folds spared ☐
- widespread ☐
- face ☐
- other: _____ ☐
  (please specify)

	no	yes	unknown	date of onset	date of resolution*
Blisters / epidermal sheets > 5cm	☐	☐	☐	☐☐☐☐☐☐	☐☐☐☐☐☐

If yes,

Maximum of detachment (percentage related to the BSA) ☐☐☐

	no	yes	unknown	date of onset	date of resolution*
Postpustular desquamation	☐	☐	☐	☐☐☐☐☐☐	☐☐☐☐☐☐

* if cured before interview

Interview no. ☐☐☐ ☐☐☐☐

FOR CASES OF AGEP ONLY

MUCOSAL EROSIONS

	no	yes	unknown	date of onset	date of resolution*
Lips	☐	☐	☐	☐☐☐☐☐☐	☐☐☐☐☐☐
Mouth	☐	☐	☐	☐☐☐☐☐☐	☐☐☐☐☐☐
Eyes	☐	☐	☐	☐☐☐☐☐☐	☐☐☐☐☐☐
Genital	☐	☐	☐	☐☐☐☐☐☐	☐☐☐☐☐☐
Anal	☐	☐	☐	☐☐☐☐☐☐	☐☐☐☐☐☐
Nasal	☐	☐	☐	☐☐☐☐☐☐	☐☐☐☐☐☐

LABORATORY FINDINGS

- Leucocytes

	not done	date of maximum
On admission**:** _____ /µl	☐	
Maximum: _____ /µl	☐	☐☐☐☐☐☐

- Neutrophils

	not done	date of maximum
On admission**:** _____ /µl	☐	
Maximum: _____ /µl	☐	☐☐☐☐☐☐

- Eosinophils

	not done	date of maximum
On admission**:** _____ /µl	☐	
Maximum: _____ /µl	☐	☐☐☐☐☐☐

*if cured before interview

Interview no. ☐☐☐ ☐☐☐☐

FOR ALL CASES

FURTHER INFORMATION FOR CASE VALIDATION

	no	yes	unknown	date of first occurrence
Photographs	☐	☐	☐	☐☐☐☐☐☐
Biopsy	☐	☐	☐	☐☐☐☐☐☐
Diagnosis by a dermatologist	☐	☐	☐	☐☐☐☐☐☐

If yes, please specify: _____

Further photographs:

Date	Notes
_____	_____
_____	_____
_____	_____

SCORTEN-PARAMETERS (within 3 days after admission)

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

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

Interview no. ☐☐☐ ☐☐☐☐

SYMPTOMS / EVENTS WITHIN 1 MONTH BEFORE THE RECENT SKIN REACTION

Infections

	no	yes	unknown	date of onset	date of normalization*
If yes,					
- influenza / influenza-like illness		☐		☐☐☐☐☐☐	☐☐☐☐☐☐
- rhinopharyngitis / common cold		☐		☐☐☐☐☐☐	☐☐☐☐☐☐
- tonsillitis		☐		☐☐☐☐☐☐	☐☐☐☐☐☐
- sinusitis		☐		☐☐☐☐☐☐	☐☐☐☐☐☐
- acute otitis		☐		☐☐☐☐☐☐	☐☐☐☐☐☐
- acute bronchitis		☐		☐☐☐☐☐☐	☐☐☐☐☐☐
- pneumonia		☐		☐☐☐☐☐☐	☐☐☐☐☐☐
- acute gastroenteritis		☐		☐☐☐☐☐☐	☐☐☐☐☐☐
- acute cystitis		☐		☐☐☐☐☐☐	☐☐☐☐☐☐
* bacterial infection proven		☐			
* prior cystitis		☐			
- other infections		☐			

	date of onset	date of normalization*
_____ (please specify)	☐☐☐☐☐☐	☐☐☐☐☐☐
_____ (please specify)	☐☐☐☐☐☐	☐☐☐☐☐☐

HIV-status

	no	yes	unknown
HIV		☐	
AIDS		☐	

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	☐	☐	☐	☐☐
- Psoriasis	☐	☐	☐	☐☐
- SCAR	☐	☐	☐	☐☐

If yes, please specify: _____

	no	yes	unknown	
Severe liver disorders?	☐	☐	☐	

If yes,

_____ ☐☐
(please specify)

	no	yes	unknown	
Severe kidney disorders?	☐	☐	☐	

If yes,

_____ ☐☐
(please specify)

	no	yes	unknown	
Rheumatic / autoimmune diseases?	☐	☐	☐	

If yes,

- rheumatoid arthritis	☐	☐☐
- systemic lupus erythematosus	☐	☐☐
- other:	☐	☐☐

If yes,

_____
(please specify)

Interview no. ☐☐☐ ☐☐☐☐

Other diseases

	no	yes	unknown	year of event
- Diabetes mellitus	☐	☐	☐	☐☐
- Convulsive disorder / epilepsy	☐	☐	☐	☐☐
- Allergic rhinitis	☐	☐	☐	☐☐
- Asthma	☐	☐	☐	☐☐
- Inflammatory bowel disease	☐	☐	☐	☐☐
* Colitis ulcerosa		☐		☐☐
* Crohn's disease		☐		☐☐
- Malignant diseases / cancer	☐	☐	☐	
If yes, please specify: _____				☐☐
If yes, please specify: _____				☐☐

Radiotherapy

	no	yes	unknown	date of most recent therapy
Have you ever had x-ray or radiotherapy? (not UV-radiation)	☐	☐	☐	☐☐☐☐☐☐

If yes, for what indication?

- lymphoma ☐ _____ (please specify)
- brain tumor ☐ _____ (please specify)
- other reason: ☐

_____ (please specify)

Interview no.

medication sheet no. ___ of ____

MEDICATION HISTORY WITHIN 1 MONTH BEFORE HOSPITALIZATION

date of admission

no drug use

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

previous intake — no / yes / unknown

If yes, any adverse reaction — no / yes / unknown

If yes, please specify: ______

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

previous intake — no / yes / unknown

If yes, any adverse reaction — no / yes / unknown

If yes, please specify: ______

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

previous intake — no / yes / unknown

If yes, any adverse reaction — no / yes / unknown

If yes, please specify: ______

Interview no.

medication sheet no. ___ of ____

MEDICATION HISTORY WITHIN 1 MONTH BEFORE HOSPITALIZATION

date of admission

no drug use

Drug / Indication	Dose	Type of application	Begin of intake (day month year)	End of intake (day month year)	Frequency
Drug ______ Indication ______					

previous intake: no / yes / unknown

If yes, any adverse reaction: no / yes / unknown

If yes, please specify: ______

Drug / Indication	Dose	Type of application	Begin of intake (day month year)	End of intake (day month year)	Frequency
Drug ______ Indication ______					

previous intake: no / yes / unknown

If yes, any adverse reaction: no / yes / unknown

If yes, please specify: ______

Drug / Indication	Dose	Type of application	Begin of intake (day month year)	End of intake (day month year)	Frequency
Drug ______ Indication ______					

previous intake: no / yes / unknown

If yes, any adverse reaction: no / yes / unknown

If yes, please specify: ______

Interview no.

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			End of intake			Frequency
			day	month	year	day	month	year	
Indication									

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

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

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

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

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

Interview no.

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: _____

Interview no. ☐☐☐ ☐☐☐☐

DISCHARGE SHEET

hospital no. ☐☐☐☐

Discharge diagnoses

1. _____

2. _____

3. _____

4. _____

5. _____

Results of the present admission

1. Death ☐ date of death ☐☐☐☐☐☐

2. Discharge ☐ date of discharge ☐☐☐☐☐☐

	no	yes	unknown	date of diagnosis
Mycoplasma infection within two months before admission	☐	☐	☐	☐☐☐☐☐☐

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?	☐	☐	☐

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)

Interview no.

ADDITIONAL REMARKS

Please use the fields below to note important additional information.

Please stick to the predefined topics and avoid redundancy:

For cases and controls:

Here you can specify additional information regarding ethnic origin:

_____

Only for cases:

Here you can specify if patient died after discharge before the follow-up or blood sampling. Please specify date of death correspondingly:

_____

_____

_____

Here you can specify any other reason why follow-up investigations/blood sampling could not be done:

_____

_____

_____

Further relevant remarks (if agreed upon by Data Center):

_____

_____

_____

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

R e g i S C A R

WEEK 8 (+/- 2 weeks)

Interview no. ☐☐☐ ☐☐☐☐

GENERAL DATA

Initials of the patient ☐☐

date of birth ☐☐☐☐☐☐

Highest temperature

date ☐☐☐☐☐☐

temperature (°C) ☐☐,☐

Date of resolution of pustules

date of resolution ☐☐☐☐☐☐

Date of resolution of erythema ☐☐☐☐☐☐

Date of resolution of desquamation ☐☐☐☐☐☐

Date of discharge

date of discharge ☐☐☐☐☐☐

Interview no. ☐☐☐ ☐☐☐☐

WEEK 8 (+/- 2 weeks)

Pathologic laboratory findings

	no	yes	unknown
Renal function	☐	☐	☐

If yes, highest pathological values: _____

	no	yes	unknown
Liver function	☐	☐	☐

If yes, highest pathological values: _____

	no	yes	unknown
Neutrophils	☐	☐	☐

If yes, highest value: _____ /mm³

Did the patient receive any systemic treatment because of the pustular disorder (only to be completed, if not stated in the discharge letter)?

Systemic therapy (steroids, other immunomodulating agents, IVIG, antibiotics)

Brand name: _____

Dosage: _____ Application: p.o. ☐ i.v. ☐

Brand name: _____

Dosage: _____ Application: p.o. ☐ i.v. ☐

Brand name: _____

Dosage: _____ Application: p.o. ☐ i.v. ☐

Brand name: _____

Dosage: _____ Application: p.o. ☐ i.v. ☐

Interview no. | | | | | | | |

WEEK 8 (+/- 2 weeks)

Additional remarks:

_____

_____

_____

Date of completion of this form: date | | | | | | |

Thank you very much for your cooperation!