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. ☐☐☐ ☐☐☐☐

SJS/TEN ☐

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:

Dokumentationszentrum schwerer Hautreaktionen (dZh)
Universitäts-Hautklinik
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D-79104 Freiburg
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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

☐ 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

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 SJS / TEN ONLY

SKIN SYMPTOMS

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

If yes,

- maculopapular / morbilliform ☐
- urticarial ☐
- large diffuse erythema (without spots) ☐
- other: _____ ☐
  (please specify)

	no	yes	unknown	date of onset
Target lesions	☐	☐	☐	☐☐☐☐☐☐

If yes,

- typical targets ☐
- atypical targets raised ☐
- atypical targets flat ☐
- spots ☐
- type of target lesions unknown ☐

<u>distribution</u>:

- mainly limbs ☐
- widespread ☐
- other: ☐

_____
(please specify)

Blisters / erosions	☐	☐	☐	☐☐☐☐☐☐
Nikolski's sign	☐	☐	☐	☐☐☐☐☐☐
Epidermal sheets > 5 cm	☐	☐	☐	☐☐☐☐☐☐

Localization of first blister / erosion: _____

		date of maximum
Maximum of erythema (percentage related to the BSA)	☐☐☐	☐☐☐☐☐☐
Maximum of detachment (percentage related to the BSA)	☐☐☐	☐☐☐☐☐☐

* if cured before admission

Interview no. ☐☐☐ ☐☐☐☐

FOR CASES OF SJS / TEN ONLY

MUCOSAL SYMPTOMS

	no	yes	unknown	date of onset	date of normalization*
Eyes	☐	☐	☐		
If yes,					
- stinging, burning		☐		☐☐☐☐☐☐	☐☐☐☐☐☐
- redness		☐		☐☐☐☐☐☐	☐☐☐☐☐☐
- severe conjunctivitis / blepharitis		☐		☐☐☐☐☐☐	☐☐☐☐☐☐
				date of diagnosis	
- diagnosis by an ophthalmologist	☐	☐	☐	☐☐☐☐☐☐	

If yes, please specify: _____

	no	yes	unknown	date of onset	date of normalization*
Lips	☐	☐	☐		
If yes,					
- burning, pain		☐		☐☐☐☐☐☐	☐☐☐☐☐☐
- swelling, edema		☐		☐☐☐☐☐☐	☐☐☐☐☐☐
- erosions, hemorrhagic crusts		☐		☐☐☐☐☐☐	☐☐☐☐☐☐

	no	yes	unknown	date of onset	date of normalization*
Oral mucosa	☐	☐	☐		
If yes,					
- burning, pain		☐		☐☐☐☐☐☐	☐☐☐☐☐☐
- redness, spots		☐		☐☐☐☐☐☐	☐☐☐☐☐☐
- erosions, hemorrhagic crusts		☐		☐☐☐☐☐☐	☐☐☐☐☐☐

* if cured before admission

Interview no. ☐☐☐ ☐☐☐☐

FOR CASES OF SJS / TEN ONLY

	no	yes	unknown		
Genital mucosa	☐	☐	☐		
If yes,				date of onset	date of normalization*
- burning, pain		☐		☐☐☐☐☐☐	☐☐☐☐☐☐
- redness, spots		☐		☐☐☐☐☐☐	☐☐☐☐☐☐
- erosions, hemorrhagic crusts		☐		☐☐☐☐☐☐	☐☐☐☐☐☐

	no	yes	unknown	date of onset	date of normalization*
Erosions of other mucosa	☐	☐	☐	☐☐☐☐☐☐	☐☐☐☐☐☐

If yes, please specify: _____

*if cured before admission

Interview no. ☐☐☐ ☐☐☐☐

FOR ALL CASES

FURTHER INFORMATION FOR CASE VALIDATION

	no	yes	unknown	date of first occurence
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

	no	yes	unknown	date of onset	date of normalization*
Infections	☐	☐	☐		
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		☐			
_____ (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 polyarthritis	☐	☐☐
- 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: _____ ☐☐

_____ ☐☐

Radiation therapy

	no	yes	unknown	date of most recent therapy
Have you ever had X-ray or radiation therapy? (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
		☐☐	☐☐☐☐☐☐	☐☐☐☐☐☐	☐
			☐☐☐☐☐☐	☐☐☐☐☐☐	☐
			☐☐☐☐☐☐	☐☐☐☐☐☐	☐

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

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

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

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

	no	yes	unknown	
previous intake	☐	☐	☐	
If yes, any adverse reaction	☐	☐	☐	**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 ____			☐☐☐☐☐☐	☐☐☐☐☐☐	☐
			☐☐☐☐☐☐	☐☐☐☐☐☐	☐

	no	yes	unknown	
previous intake	☐	☐	☐	
If yes, any adverse reaction	☐	☐	☐	**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 ____			☐☐☐☐☐☐	☐☐☐☐☐☐	☐
			☐☐☐☐☐☐	☐☐☐☐☐☐	☐

	no	yes	unknown	
previous intake	☐	☐	☐	
If yes, any adverse reaction	☐	☐	☐	**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 ____			☐☐☐☐☐☐	☐☐☐☐☐☐	☐
			☐☐☐☐☐☐	☐☐☐☐☐☐	☐

	no	yes	unknown	
previous intake	☐	☐	☐	
If yes, any adverse reaction	☐	☐	☐	**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.

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)