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

RegiSCAR

Case Record Form

Interview no.

SJS/TEN ☐

EEMM ☐

GBFDE ☐

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:

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
(only for DRESS)

☐ 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)	method of measurement
		.	
		.	

* if cured before admission

Interview no. ☐☐☐ ☐☐☐☐

FOR CASES OF SJS/TEN, EEMM, GBFDE ONLY

SKIN SYMPTOMS

	no	yes	unknown	date of onset	date of normalization*
Burning	☐	☐	☐	☐☐☐☐☐☐	☐☐☐☐☐☐
Pain	☐	☐	☐	☐☐☐☐☐☐	☐☐☐☐☐☐
Pruritus	☐	☐	☐	☐☐☐☐☐☐	☐☐☐☐☐☐
Erythema, exanthema (other than targets/spots below)	☐	☐	☐	☐☐☐☐☐☐	☐☐☐☐☐☐

If yes,

	yes		yes
- urticarial	☐	- large diffuse erythema (without spots)	☐
- unknown	☐		
- other:	☐		

____
(please specify)

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

If yes,

- Typical targets	☐	Distribution	☐
- Atypical targets raised	☐	- mainly limbs	☐
- Atypical targets flat	☐	- widespread	☐
- Spots	☐	- other:_________________	☐
- Type of targets lesions unknown	☐	- unknown	☐

* If cured before admission

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FOR CASES OF SJS/TEN, EEMM, GBFDE ONLY

	no	yes	unknown	date of onset
Erythema patches, ≥ 5cm	☐	☐	☐	☐☐☐☐☐☐

If yes,

		yes		yes
- brownish/violacous		☐	- well demarcated	☐
Distribution/number	- <5	☐	- >10	☐
	- 5-10	☐	- different body parts	☐

	no	yes	unknown	date of onset
Blisters/erosions	☐	☐	☐	☐☐☐☐☐☐
Nikolski's sign	☐	☐	☐	☐☐☐☐☐☐
Epidermal sheets > 5cm	☐	☐	☐	☐☐☐☐☐☐

Localization of first blister/erosion:____

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

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FOR CASES OF SJS/TEN, EEMM, GBFDE ONLY

MUCOSAL SYMPTOMS

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

If yes,
- severe conjunctivitis / blepharitis ☐
- other diagnosis: ____________________

	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, EEMM, GBFDE ONLY

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

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

If yes,

- nasal ☐
- anal ☐
- tracheal / bronchial ☐
- other: ______________________________

SCORTEN-PARAMETERS (within 3 days after admission)

	no	yes	not done	unknown
- 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	☐	☐	☐	☐

* if cured before admission

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 / biopsies and comments:

Date	Notes
____________	____
____________	____
____________	____
____________	____
____________	____

Interview no. ☐☐☐ ☐☐☐☐

SYMPTOMS / EVENTS WITHIN 1 MONTH BEFORE THE RECENT SKIN REACTION

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

Do you have recurrent herpes labialis or fever blisters?

no	yes	unknown	date of last eruption
☐	☐	☐	☐☐☐☐☐☐

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

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		☐		☐☐☐☐☐☐	☐☐☐☐☐☐
Was the diagnosis confirmed by a physician?		☐			
Was any diagnostic test performed?		☐			
Was any medication taken for treatment?		☐			
- respiratory tract infection		☐		☐☐☐☐☐☐	☐☐☐☐☐☐
Was the diagnosis confirmed by a physician?		☐			
Was any diagnostic test performed?		☐			
Was any medication taken for treatment?		☐			
- urinary tract infection		☐		☐☐☐☐☐☐	☐☐☐☐☐☐
Was the diagnosis confirmed by a physician?		☐			
Was any diagnostic test performed?		☐			
Was any medication taken for treatment?		☐			
- other infection 1		☐		☐☐☐☐☐☐	☐☐☐☐☐☐
____________ (please specify)					
Was the diagnosis confirmed by a physician?		☐			
Was any diagnostic test performed?		☐			
Was any medication taken for treatment?		☐			
- other infection 2		☐		☐☐☐☐☐☐	☐☐☐☐☐☐
____________ (please specify)					
Was the diagnosis confirmed by a physician?		☐			
Was any diagnostic test performed?		☐			
Was any medication taken for treatment?		☐			

*if cured before admission

HIV-status	no	yes	unknown
HIV	☐	☐	☐
AIDS (current status)	☐	☐	☐

If yes for HIV or AIDS,

most recent CD4 count per µl: ☐☐☐

*if cured before admission

Interview no.

HAVE YOU HAD ANY OF THE FOLLOWING DISEASES THAT ARE STILL ACTIVE?

	no	yes	unknown	year of event
Severe liver disorders	☐	☐	☐	☐☐☐☐

If yes, ____________________ (please specify)

	no	yes	unknown	year of event
Severe kidney disorders	☐	☐	☐	☐☐☐☐

If yes, ____________________ (please specify)

	no	yes	unknown	year of event
Rheumatic / collagen-vascular disease	☐	☐	☐	
If yes,				
- rheumatoid polyarthritis		☐		☐☐☐☐
- systemic lupus erythematosus		☐		☐☐☐☐
- other:		☐		☐☐☐☐

If yes, ____________________ (please specify)

	no	yes	unknown
Was a first-degree family member diagnosed with any rheumatic/ collagen-vascular disease?	☐	☐	☐

	no	yes	unknown	year of event
Inflammatory bowel disease	☐	☐	☐	
- Colitis ulcerosa		☐		☐☐☐☐
- Crohn's disease		☐		☐☐☐☐

	no	yes	unknown	year of event
Psoriasis	☐	☐	☐	☐☐☐☐
- Pustular psoriasis, generalized		☐		

	no	yes	unknown
Was a first-degree family member diagnosed with psoriasis?	☐	☐	☐

	no	yes	unknown	year of event
Convulsive disorder / epilepsy	☐	☐	☐	☐☐☐☐

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HAVE YOU BEEN DIAGNOSED WITH A MALIGNANT DISEASE/CANCER WITHIN THE LAST 2 YEARS BEFORE THE REACTION OR THAT IS STILL BEING TREATED?

	no	yes	unknown	year of event
Malignant diseases / cancer	☐	☐	☐	
If yes, please specify: ______________________				☐☐☐☐
If yes, please specify: ______________________				☐☐☐☐

HAVE YOU HAD ANY RADIOTHERAPY RECENTLY?

	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)

HAVE YOU IN THE PAST HAD ANY TRANSPLANTATION?

	no	yes	unknown	year of transplantation
Transplantation	☐	☐	☐	☐☐☐☐

If yes,

- Stem cell ☐

- other: ______________________ ☐

HAVE YOU IN THE PAST HAD ANY SCAR?

	no	yes	unknown	year of event
SCAR	☐	☐	☐	☐☐☐☐

If yes, please specify: ______________________ (please specify)

medication sheet no.___of___

Interview no

MEDICATION HISTORY WITHIN 1 MONTH BEFORE HOSPITALIZATION

date of admission

drug use: no ☐ yes ☐ unknown ☐

Drug / Indication	Type of application	Dose	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	Type of application	Dose	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	Type of application	Dose	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: ______

medication sheet no.___of___

Interview no

MEDICATION HISTORY WITHIN 1 MONTH BEFORE HOSPITALIZATION

date of admission

drug use: no / yes / unknown

Drug ____________ Indication ____________	Type of application	Dose	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 ____________	Type of application	Dose	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 ____________	Type of application	Dose	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: ____________

medication sheet no.___of___

Interview no

MEDICATION HISTORY WITHIN 1 MONTH BEFORE HOSPITALIZATION

date of admission

drug use no yes unknown

Drug Indication	Type of application	Dose	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	Type of application	Dose	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	Type of application	Dose	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:

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Have you ever had a rash / skin reaction suspected to be an adverse reaction to a drug?

no	yes	unknown
☐	☐	☐

If yes,

Drug: ____________________

Type of eruption: ____________________

Drug: ____________________

Type of eruption: ____________________

Drug: ____________________

Type of eruption: ____________________

Drug: ____________________

Type of eruption: ____________________

Drug: ____________________

Type of eruption: ____________________

Interview no.

DISCHARGE SHEET

Discharge diagnoses

1. ______________________________

2. ______________________________

3. ______________________________

4. ______________________________

5. ______________________________

Results of the present admission

		date of death
1. Death	☐	☐☐☐☐☐☐

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

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

If no or yes, by which diagnostic means was the diagnosis reached:

- ☐ serology
- ☐ isolation
- ☐ x-ray
- ☐ PCR
- ☐ unknown

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: ________________________

Interview no.

ADDITIONAL REMARKS (optional)

Please use the fields below to note important additional information.

Please stick to the predefined topics and avoid redundancy:

Here you can specify additional information regarding ethnic origin:

____

Here you can indicate if patient died after discharge. Please provide date of death:

Death ☐ date

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

____

____

____

Further relevant remarks:

____

____

____

Interview no. ☐☐☐ ☐☐☐☐

THERAPY 1

TREATING HOSPITAL

hospital no. ☐☐☐☐ date of admission ☐☐☐☐☐☐

____

1. Burn unit ☐
2. Dept. of dermatology ☐
3. Intensive care unit ☐
4. Pediatric department ☐
5. Internal medicine ☐
6. Other: ☐

____
(please specify)

SYSTEMIC THERAPY

1) Corticosteroids no ☐ yes ☐ unknown ☐

If yes,
please enter: starting date ☐☐☐☐☐☐ stopping date ☐☐☐☐☐☐

Brand name/drug: ____

____

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

(if varying please provide minimum and maximum)

Comment: ____

____

2) IVIG no ☐ yes ☐ unknown ☐

If yes,
please enter: starting date ☐☐☐☐☐☐ stopping date ☐☐☐☐☐☐

Brand name/drug: ____

____

Dosage: ____

(if varying please provide minimum and maximum)

Comment: ____

____

Interview no.

THERAPY 2

3) Ciclosporin no yes unknown

If yes,
please enter: starting date stopping date

Brand name/drug:

Dosage:

(if varying please provide minimum and maximum)

Comment:

4) Other systemic treatments no yes unknown

If yes,
please enter: starting date stopping date

Brand name/drug:

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

(if varying please provide minimum and maximum)

Comment:

If yes,
please enter: starting date stopping date

Brand name/drug:

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

(if varying please provide minimum and maximum)

Comment:

Interview no.

THERAPY 3

5) Antibiotics no ☐ yes ☐ unknown ☐ starting date

If yes,

- did the patient developed septicaemia? ☐ date of diagnosis

TRANSFER TO OTHER HOSPITAL OR DEPARTMENT FOR TREATMENT OF SCAR

no ☐ yes ☐

If yes, please complete the sheet for the second treating hospital.