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 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)
- unknown ☐

<u>localization of exanthema</u>:

- mainly folds ☐
- widespread ☐
- face ☐
- other: ☐

_____
(please specify)

unknown ☐

Maximum extent of exanthema ☐☐☐
(percentage related to the BSA)

	no	yes	unknown	date of onset	date of resolution*
Facial edema	☐	☐	☐	☐☐☐☐☐☐	☐☐☐☐☐☐

* if cured before <u>discharge / death of patient</u>
(if information of grey marked fields could not observed before discharge please try to verify information via phone call)

Interview no. ☐☐☐ ☐☐☐☐

FOR CASES OF AGEP ONLY

	no	yes	unknown	date of onset	date of resolution*
Pustules	☐	☐	☐		
If yes,					
- few (< 25)		☐		☐☐☐☐☐☐	☐☐☐☐☐☐
- many (≥ 25; dozens)		☐		☐☐☐☐☐☐	☐☐☐☐☐☐
- unknown		☐			
Type of pustules:					
- follicular		☐		☐☐☐☐☐☐	☐☐☐☐☐☐
- non-follicular		☐		☐☐☐☐☐☐	☐☐☐☐☐☐
- unknown type of pustules		☐		☐☐☐☐☐☐	☐☐☐☐☐☐
Localization of pustules:					
- mainly folds		☐			
- folds spared		☐			
- widespread		☐			
- face		☐			
- other: _____ (please specify)		☐			
- unknown		☐			

	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 discharge / death of patient
(if information of grey marked fields could not observed before discharge please try to verify information via phone call)

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	☐	☐☐☐☐☐☐

	no	yes	unknown
- Pathological renal-function	☐	☐	☐

If yes, highest pathological values: _____

	no	yes	unknown
- Pathological liver-function	☐	☐	☐

If yes, highest pathological values: _____

* if cured before discharge / death of patient

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

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		☐		☐☐☐☐☐☐	☐☐☐☐☐☐
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)					

*if cured before admission

Was the diagnosis confirmed by a physician?		☐	
Was any diagnostic test performed?		☐	
Was any medication taken for treatment?		☐	

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
Rheumatic / collagen-vascular disease	☐	☐	☐

If yes,

	yes	year of event
- 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
Inflammatory bowel disease	☐	☐	☐

	yes	year of event
- 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	☐	☐	☐	☐☐☐☐

Interview no. ☐☐☐ ☐☐☐☐

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

previous intake: no / yes / unknown

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

If yes, please specify: ________

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

previous intake: no / yes / unknown

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

If yes, please specify: ________

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

	no	yes	unknown
drug use	☐	☐	☐

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

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: ______

Interview no. ☐☐☐ ☐☐☐☐

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

1. Death ☐ date of death ☐☐☐☐☐☐

2. Discharge ☐ date of 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. ☐☐☐ ☐☐☐☐

FOR CASES OF AGEP ONLY

THERAPY

UNIT OF TREATMENT

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

_____
(please specify)

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, retinoids and anti-TNF)

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. ☐