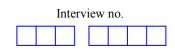
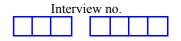
REGISTRY OF SEVERE CUTANEOUS ADVERSE REACTIONS TO DRUGS AND COLLECTION OF BIOLOGICAL SAMPLES

RegiSCAR



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 |



HOSPITAL DATA

| Reporting | g hospital / department | hospital no. | date of admission |
|--------------|--|------------------------|-------------------|
| Treating | hospital / department | hospital no. | date of admission |
| date of noti | fication | | date of interview |
| Transfer | from one or more hospitals to the reportin | g / treating hospital: | |
| | no | | |
| | yes | | |
| | unknown | | |
| | If yes, first hospital: | hospital no. | date of admission |
| | | | |
| Retrospe | ctive assessment | | |
| | no | | |
| | yes | | |
| Developm | nent of skin reaction | | |
| | prior to admission | | |
| | during inhospital stay | | |

DIAGNOSES AND CLINICAL COURSE

| Admission | diagnoses |
|-----------|-----------|
|-----------|-----------|

| 1) | | |
|----|------|------|
| 2) | | |
| 3) | | |

| Date | Clinical symptom | ns | | | |
|---------------|------------------|-----------------------|---------|----------------------|-----------------------|
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| Fever | no | yes un | xnown | | |
| If yes, | | | | | |
| date of onset | | date of normalization | n* high | est temperature (°C) | method of measurement |
| | | | | | |
| | | | | | |

* if cured before admission

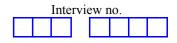
SKIN SYMPTOMS

| Subjective symptoms |
|---------------------|
|---------------------|

| Burning | no | yes | unknown | date of onset | | date of reso | olution* |
|--|-----|-----|---------|---------------|-------------------|---------------|-----------------|
| Pain | | | | | | | |
| Pruritus | | | | | | | |
| Erythema, exanthema | | | | | | | |
| If yes, | | | | | | | |
| - diffuse erythema | | | | | <u>localizati</u> | on of exa | <u>nthema</u> : |
| - urticarial | | | | | mainly f | olds | |
| - maculopapular | | | | | widespre | ead | |
| - purpura | | | | | face | | |
| - target lesions | | | | | other: | | |
| - other: | | | | | | | |
| (please specify) | | | | | (ple | ease specify | 7) |
| - unknown | | | | | unknown | 1 | |
| Maximum extent of exanthema (percentage related to the BSA) | a [| | | | | | |
| Facial edema | no | yes | unknown | date of onset | | date of resol | ution* |
| | | | | | | | |

Interview no.

* 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)



| Pustules | no | yes | unknown | | |
|--|----|-----|---------|---------------|---------------------|
| If yes, | | | | | |
| - few (< 25) | | | | date of onset | date of resolution* |
| - many (\geq 25; dozens) | | | | | |
| - unknown | | | | | |
| <u>Type of pustules</u> : | | | | | |
| - follicular | | | | | |
| - non-follicular | | | | | |
| - unknown type of pustules | | | | | |
| Localization of pustules: | | | | | |
| - mainly folds | | | | | |
| - folds spared | | | | | |
| - widespread | | | | | |
| - face | | | | | |
| - other:(please specify) | | | | | |
| - unknown | | | | | |
| | | | | | |
| Blisters / epidermal sheets > 5cm | no | yes | unknown | date of onset | date of resolution* |
| If yes, | | | | | |
| Maximum of detachment (percentage related to the BSA) | | | | | |
| Postpustular desquamation | no | yes | unknown | date of onset | date of resolution* |

* 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. | | | | | | | |
|---------------|--|--|--|--|--|--|--|
| | | | | | | | |

MUCOSAL EROSIONS

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

LABORATORY FINDINGS

| - Leucocytes | | not done | | |
|--------------------------------------|----|----------|---------|-----------------|
| On admission:/µl | | | | |
| Maximum:/µl | | | | date of maximum |
| - Neutrophils | | not done | | |
| On admission:/µl | | | | |
| Maximum:/µl | | | | date of maximum |
| - Eosinophils | | not done | | |
| On admission:/µl | | | | |
| Maximum:/µl | | | | date of maximum |
| - Pathological renal-function | no | yes | unknown | |
| If yes, highest pathological values: | | | | |
| - Pathological liver-function | no | yes | unknown | |
| If yes, highest pathological values: | | | | |

| Interview no. | | | | | | | |
|---------------|--|--|--|--|--|--|--|
| | | | | | | | |

FOR ALL CASES

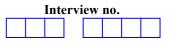
- 7 -

FURTHER INFORMATION FOR CASE VALIDATION

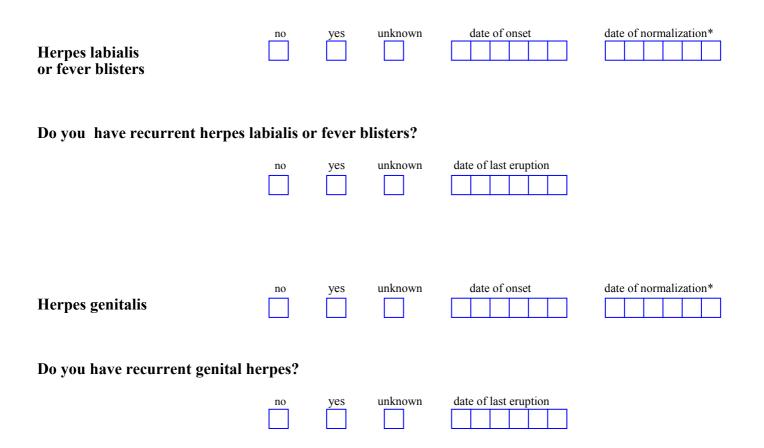
| Photographs | no | yes | unknown | date of first occurrence |
|------------------------------|----|-----|---------|--------------------------|
| Biopsy | | | | |
| Diagnosis by a dermatologist | | | | |
| If yes, please specify: | | | | |

Further photographs / biopsies and comments:

| Date | Notes |
|------|-------|
| | |
| | |
| | |
| | |
| | |



SYMPTOMS / EVENTS WITHIN 1 MONTH BEFORE THE RECENT SKIN REACTION



*if cured before admission

- 9 -

| Interview no. | | | | | | | | | | |
|---------------|--|--|--|--|--|--|--|--|--|--|
| | | | | | | | | | | |

*if cured before admission

SYMPTOMS / EVENTS WITHIN 1 MONTH BEFORE THE RECENT SKIN REACTION

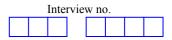
| Infections If yes, | no | yes | unknown | l | | | | | | | |
|--|----|-----|---------|---|-----|----------|-----|--------|----------|----------|---------|
| - influenza / influenza-like illness | | | | | dat | e of ons | set | date o | of norma | lization | * |
| Was the diagnosis confirmed by a physician? 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 be | fore adr | nission |
| 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: | | | | | | | | | | | |

2012-12-20



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

| Severe liver d | lisorders | no | yes | unknown | year of event |
|------------------------------|---|----|-----|---------|---------------|
| If yes, | (please specify) | | | | |
| Severe kidney | y disorders | no | yes | unknown | year of event |
| If yes, | (please specify) | | | | |
| Rheumatic / o | collagen-vascular disease | no | yes | unknown | |
| If yes, | | | | | |
| - rheumatoid p | oolyarthritis | | | | year of event |
| - systemic lup | us erythematosus | | | | |
| - other: | | | | | |
| If yes, | | | | | |
| | (please specify) gree family member h any rheumatic/ ular disease? | no | yes | unknown | |
| Inflammator | y bowel disease | no | yes | unknown | |
| - Colitis ulcere | osa | | | | year of event |
| - Crohn's disea | ase | | | | |
| D • • | | no | yes | unknown | year of event |
| Psoriasis | | | | | |
| - Pustular psor | riasis, generalized | | | | |
| Was a first-de diagnosed wit | gree family member h psoriasis? | no | yes | unknown | |
| Convulsive d | isorder / epilepsy | no | yes | unknown | year of event |



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

| Malignant diseases / cancer | no | yes | unknown | |
|--|---------------------|-------|-----------|-------------------------|
| If yes, please specify: | | | | year of event |
| If yes, please specify: | | | | |
| HAVE YOU HAD ANY RADIOTHEI | RAPY RI | ECENT | LY? | date of most |
| Have you ever had X-ray or radiotherapy? (not UV-radiation) | no | yes | unknown | recent therapy |
| If yes, for what indication? | | | | |
| - lymphoma | | | (please s | specify) |
| - brain tumor | | | (please s | specify) |
| - other reason: | | | 4 | , |
| (please specify) | | | | |
| HAVE YOU IN THE PAST HAD AN | Y TRAN | SPLAN | | |
| Transplantation | no | yes | unknown | year of transplantation |
| If yes, | | | | |
| - Stem cell | | | | |
| - other: | | | | |
| HAVE YOU IN THE PAST HAD AN | Y SCAR ⁴ | yes | unknown | year of event |
| SCAR | | | | |
| If yes, please specify: | fy) | | | |

Interview no

| MEDICATION HIST | ORY WIT | HIN 1 M | IONTH BEFORE | HOSPITALIZATI | |
|------------------------------|---------------------|---------|-----------------|-------------------------|-----------|
| date of admission | | | drug us | e no yes | unknown |
| Drug | Type of application | Dose | Begin of intake | End of intake | Frequency |
| | approation | | day month year | day month year | |
| | | | | | |
| Indication | | | | | |
| | | | | | |
| previous intake | no | yes | unknown | <u> </u> | |
| 1 | no | yes | unknown | If yes, please specify: | |
| If yes, any adverse reaction | | yes | | n yes, please speeny. | |
| | | | | | |
| Drug | Type of application | Dose | Begin of intake | End of intake | Frequency |
| | apprication | | day month year | day month year | |
| | | | | | |
| Indication | | | | | |
| | | | | | |
| previous intake | no | yes | unknown | - | |
| | no | yes | unknown | If yes, please specify: | |
| If yes, any adverse reaction | | | | | |
| | | - | | | |
| Drug | Type of application | Dose | Begin of intake | End of intake | Frequency |
| | | | day month year | day month year | |
| Indication | | | | | |
| Indication | | | | | |
| | | | | | |
| provious inteles | no | yes | unknown | 1 | |
| previous intake | | | | | |
| If yes, any adverse reaction | no | yes | unknown | If yes, please specify: | |

Interview no

| MEDICATION HIST date of admission | ORY WIT | HIN 1 M | | no yes | ON unknown |
|--------------------------------------|---------------------|---------|-----------------|-------------------------|---------------|
| | | | drug us | | |
| 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 |
| | upphounten | | 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 | Dose | Begin of intake | End of intake | Frequency |
| | application | | day month year | day month year | |
| | | | | | |
| Indication | | | | | |
| | | | | | |
| previous intake | no | yes | unknown | | |
| If yes, any adverse reaction | no | yes | unknown | If yes, please specify: | |

Interview no

| MEDICATION HIST | ORY WIT | HIN 1 M | IONTH BEFORE | no yes | ON unknown |
|------------------------------|---------------------|---------|-----------------------------------|---------------------------------|---------------|
| Drug | Type of application | Dose | 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 | Type of application | Dose | 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 | Type of application | Dose | 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: | |

| 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: | | | |



DISCHARGE SHEET

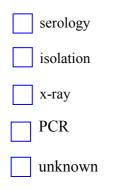
Discharge diagnoses

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



| Interview no. | | | | | | | |
|---------------|--|--|--|--|--|--|--|
| | | | | | | | |

MAIN SOURCE OF INFORMATION

1) Clinical pattern of the reaction

| * Were the skin lesions seen by investigator in acute stage? | the | no | yes | unknown |
|--|-----|----------------|--------------|---------|
| If not, please provide the sou (e.g., family physician, | | family member) | | |
| | | | | |
| 2) Medication history | | | | |
| * just patient | | | | |
| * just other source | | If yes, plea | ise specify: | |
| * both | | If yes, plea | se 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:

THERAPY

UNIT OF TREATMENT

| Burn unit | |
|----------------------|--|
| Dept. of dermatology | |
| Intensive care unit | |
| Pediatric department | |
| Internal medicine | |
| Other: | |
| | Dept. of dermatology Intensive care unit Pediatric department Internal medicine |

(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 a | nti-TN | F) | | |
|--|-----------------|--------|----|------|--|
| 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.