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

Follow-up
Week 8 (+/- 2 weeks)

Interview no. ☐☐☐ ☐☐☐☐

HSS/DRESS ☐

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
Hauptstr. 7
D-79104 Freiburg
Tel. 0761 270-6723

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

Date of follow-up
☐☐☐☐☐☐

Initials of the patient
☐☐

date of birth
☐☐☐☐☐☐

Result of the last admission

1. Death ☐ date of death ☐☐☐☐☐☐

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

Artificial ventilation during hospital course

no ☐ yes ☐ unknown ☐

Did you resume your normal activity?

no ☐ yes ☐ unknown ☐

If yes, please enter date: ☐☐☐☐☐☐

Interview no. ☐☐☐ ☐☐☐☐

WEEK 8 (+/- 2 weeks)

DERMATOLOGIC EXAMINATION

	no	yes	date of reepithelization
Cutaneous erosions	☐	☐	☐☐☐☐☐☐
Erythema	☐	☐	
Scales and desquamation	☐	☐	
Hypertrophic scars	☐	☐	
Hyperpigmentation	☐	☐	
Hypopigmentation	☐	☐	
Hair loss	☐	☐	
Nail loss	☐	☐	

Skin symptoms <u>within 2 weeks prior to follow-up</u>

	no	yes	unknown
Burning skin	☐	☐	☐
Pruritus	☐	☐	☐
Other	☐	☐	☐

If yes, please specify:

_____

Interview no. ☐☐☐ ☐☐☐☐

WEEK 8 (+/- 2 weeks)

INVOLVEMENT OF MUCOSAE

	no	yes	unknown
Lips			
- pain	☐	☐	☐
- erosions	☐	☐	☐
- crusts	☐	☐	☐
Mouth			
- pain	☐	☐	☐
- erosions	☐	☐	☐
- dryness	☐	☐	☐
- synechiae	☐	☐	☐
- impairment of taste	☐	☐	☐
Genitalia			
- pain	☐	☐	☐
- erosions	☐	☐	☐
- dryness	☐	☐	☐
- synechiae	☐	☐	☐
- dyspareunia	☐	☐	☐
Other mucous membranes			
If yes, please specify:	☐	☐	☐

_____

Eyes

Are you followed by an ophthalmologist?

no ☐ yes ☐

If yes, when was the last examination? date ☐☐☐☐☐☐

Do you agree that we obtain information from your ophthalmologist?

no ☐ yes ☐

If yes, please provide name and address to the interviewer:

_____

_____

Interview no. ☐☐☐ ☐☐☐☐

WEEK 8 (+/- 2 weeks)

Right eye

	no	yes	unknown
- watering	☐	☐	☐
- dryness	☐	☐	☐
- pain	☐	☐	☐
- photophobia	☐	☐	☐
- redness	☐	☐	☐
- conjunctival erosions	☐	☐	☐
- corneal lesions	☐	☐	☐
- synechiae	☐	☐	☐
- loss of eyelashes	☐	☐	☐
- trichiasis	☐	☐	☐
- visual impairment related to SCAR	☐	☐	☐

If yes, visual acuity: ☐☐

Left eye

	no	yes	unknown
- watering	☐	☐	☐
- dryness	☐	☐	☐
- pain	☐	☐	☐
- photophobia	☐	☐	☐
- redness	☐	☐	☐
- conjunctival erosions	☐	☐	☐
- corneal lesions	☐	☐	☐
- synechiae	☐	☐	☐
- loss of eyelashes	☐	☐	☐
- trichiasis	☐	☐	☐
- visual impairment related to SCAR	☐	☐	☐

If yes, visual acuity: ☐☐

Interview no. ☐☐☐ ☐☐☐☐

WEEK 8 (+/- 2 weeks)

Were there any of the following symptoms?

	no	yes		no/cured	yes
Lymph nodes > 1cm	☐	☐	**If yes,** still present:		☐
			If cured, date of normalization:	☐☐☐☐☐☐	
Edemas	☐	☐	**If yes,** still present:		☐
			If cured, date of normalization:	☐☐☐☐☐☐	
Pulmonary involvement	☐	☐	**If yes,** still present:		☐
			If cured, date of normalization:	☐☐☐☐☐☐	
Liver involvement	☐	☐	**If yes,** still present:		☐
			If cured, date of normalization:	☐☐☐☐☐☐	
Kidney involvement	☐	☐	**If yes,** still present:		☐
			If cured, date of normalization:	☐☐☐☐☐☐	
Myocarditis	☐	☐	**If yes,** still present:		☐
			If cured, date of normalization:	☐☐☐☐☐☐	
Pericarditis	☐	☐	**If yes,** still present:		☐
			If cured, date of normalization:	☐☐☐☐☐☐	
Pleuritis	☐	☐	**If yes,** still present:		☐
			If cured, date of normalization:	☐☐☐☐☐☐	
Arthritis	☐	☐	**If yes,** still present:		☐
			If cured, date of normalization:	☐☐☐☐☐☐	
Colitis	☐	☐	**If yes,** still present:		☐
			If cured, date of normalization:	☐☐☐☐☐☐	
Other, please specify:					
_____	☐	☐	**If yes,** still present:		☐
			If cured, date of normalization:	☐☐☐☐☐☐	
_____	☐	☐	**If yes,** still present:		☐
			If cured, date of normalization:	☐☐☐☐☐☐	

Interview no. ☐☐☐ ☐☐☐☐

WEEK 8 (+/- 2 weeks)

ONLY FOR HSS / DRESS: LABORATORY FINDINGS 1

Blood Count

	no	yes	not done	
- Hemoglobin < 10 g/dl	☐	☐	☐	
If yes, lowest value: _____ g/dl				date of worst value ☐☐☐☐☐☐
- Platelets < 100000 /µl	☐	☐	☐	
If yes, lowest value: _____ /µl				☐☐☐☐☐☐
- Neutrophils < 1500 /µl	☐	☐	☐	
If yes, lowest value: _____ /µl				☐☐☐☐☐☐
- Neutrophils > 7000 /µl	☐	☐	☐	
If yes, highest value: _____ /µl				☐☐☐☐☐☐
- Eosinophils > 700 /µl	☐	☐	☐	
If yes, highest value: _____ /µl				☐☐☐☐☐☐ date of normalization ☐☐☐☐☐☐
- Lymphocytes > 3000 /µl	☐	☐	☐	
If yes, highest value: _____ /µl				☐☐☐☐☐☐
- Atypical lymphocytes	☐	☐	☐	date of normalization ☐☐☐☐☐☐
- Leucocyte count	☐	☐	☐	
If yes, highest value: _____ /µl				☐☐☐☐☐☐ date of normalization ☐☐☐☐☐☐
- Leucocytes < 4000 /µl	☐	☐	☐	
If yes, lowest value: _____ /µl				☐☐☐☐☐☐ date of normalization ☐☐☐☐☐☐
AND highest count of eosinophils: _____ %				☐☐☐☐☐☐ ☐☐☐☐☐☐

Interview no. ☐☐☐☐☐☐☐

WEEK 8 (+/- 2 weeks)

ONLY FOR HSS / DRESS: LABORATORY FINDINGS 2

	no	yes	not done	date of worst value
- ALAT > 2*N	☐	☐	☐	
If yes, highest value: _____ *N				☐☐☐☐☐☐
- ASAT > 2*N	☐	☐	☐	
If yes, highest value: _____ *N				☐☐☐☐☐☐
- GGT > 2*N	☐	☐	☐	
If yes, highest value: _____ *N				☐☐☐☐☐☐
- Alk. phosphatase > 1,5*N	☐	☐	☐	
If yes, highest value: _____ *N				☐☐☐☐☐☐
- CK > 1*N	☐	☐	☐	
If yes, highest value: _____ *N				☐☐☐☐☐☐
- CK-MB > 1*N	☐	☐	☐	
If yes, highest value: _____ *N				☐☐☐☐☐☐
- Troponin > 1*N	☐	☐	☐	
If yes, highest value: _____ *N				☐☐☐☐☐☐
- LDH > 1*N	☐	☐	☐	
If yes, highest value: _____ *N				☐☐☐☐☐☐
- Prothrombin time abnormal	☐	☐	☐	
If yes, lowest value: _____ %				☐☐☐☐☐☐
- Quick's value abnormal	☐	☐	☐	
If yes, lowest value: _____ %				☐☐☐☐☐☐
- Creatinin > 1,5*N	☐	☐	☐	
If yes, highest value: _____ *N				☐☐☐☐☐☐
- Urea > 10 mmol/l	☐	☐	☐	
If yes, highest value: _____ mmol/l				☐☐☐☐☐☐

Interview no. ☐☐☐ ☐☐☐☐

WEEK 8 (+/- 2 weeks)

ONLY FOR HSS / DRESS: LABORATORY FINDINGS 3

	no	yes	not done
- Proteinuria > 0,5 g/24h	☐	☐	☐

If yes, highest value: _____ g/24h

- Hematuria > 10000 /ml	☐	☐	☐
- Leucocyturia > 10000 /ml	☐	☐	☐
- Abnormal blood gases	☐	☐	☐

If yes, please specify:

_____ date of worst value ☐☐☐☐☐☐ date of normalization ☐☐☐☐☐☐

- Other abnormal laboratory values	☐	☐	☐

If yes, please specify:

_____ date of worst value ☐☐☐☐☐☐ date of normalization ☐☐☐☐☐☐

If yes, please specify:

_____ date of worst value ☐☐☐☐☐☐ date of normalization ☐☐☐☐☐☐

Interview no. ☐☐☐ ☐☐☐☐

WEEK 8 (+/- 2 weeks)

ONLY FOR HSS / DRESS: LABORATORY FINDINGS 4

Serology

	positive	negative	not done	date of diagnosis
- Hepatitis A	☐	☐	☐	☐☐☐☐☐☐
- Hepatitis B	☐	☐	☐	☐☐☐☐☐☐
- Hepatitis C	☐	☐	☐	☐☐☐☐☐☐
- EBV	☐	☐	☐	☐☐☐☐☐☐
- CMV	☐	☐	☐	☐☐☐☐☐☐
- Chlamydia	☐	☐	☐	☐☐☐☐☐☐
- Mycoplasma	☐	☐	☐	☐☐☐☐☐☐
- HHV-6	☐	☐	☐	☐☐☐☐☐☐
- Other	☐	☐	☐	☐☐☐☐☐☐

If yes, please specify

_____

Blood culture ☐ ☐ ☐ ☐☐☐☐☐☐

ANA ☐ ☐ ☐ ☐☐☐☐☐☐

Interview no. ☐☐☐ ☐☐☐☐

WEEK 8 (+/- 2 weeks)

ONLY FOR HSS / DRESS: MEDICAL IMAGING AND BIOPSIES

	no	yes	unknown
- Abnormal chest-CT	☐	☐	☐

If yes, please specify: date of diagnosis ☐☐☐☐☐☐

_____

- Abnormal bronchial endoscopy	☐	☐	☐

If yes, please specify:

_____ ☐☐☐☐☐☐

- Abnormal cardiac sonography	☐	☐	☐

If yes, please specify:

_____ ☐☐☐☐☐☐

- Abnormal gastrointest. endoscopy	☐	☐	☐

If yes, please specify:

_____ ☐☐☐☐☐☐

- Abnormal abdominal sonography	☐	☐	☐

If yes, please specify:

_____ ☐☐☐☐☐☐

- Abnormal other imaging (CT/MRI)	☐	☐	☐

If yes, please specify:

_____ ☐☐☐☐☐☐

- Abnormal liver biopsy	☐	☐	☐

If yes, please specify:

_____ date of biopsy ☐☐☐☐☐☐

- Abnormal kidney biopsy	☐	☐	☐

If yes, please specify:

_____ ☐☐☐☐☐☐

- Abnormal biopsy of other organ	☐	☐	☐

If yes, please specify:

_____ ☐☐☐☐☐☐

Interview no. ☐☐☐☐☐☐☐☐

WEEK 8 (+/- 2 weeks)

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 dates: starting date ☐☐☐☐☐☐ stopping date ☐☐☐☐☐☐

Day 1 Brand name: _____

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

Day 2 Brand name: _____

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

Day 3 Brand name: _____

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

Day 4 Brand name: _____

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

Interview no. ☐☐☐☐☐☐☐☐

WEEK 8 (+/- 2 weeks)

THERAPY 2

2) IVIG

no ☐ yes ☐ unknown ☐

If yes,
please enter dates:

starting date ☐☐☐☐☐☐ stopping date ☐☐☐☐☐☐

Day 1 Brand name: _____

Dosage: _____

Day 2 Brand name: _____

Dosage: _____

Day 3 Brand name: _____

Dosage: _____

Day 4 Brand name: _____

Dosage: _____

3) Other systemic treatments

no ☐ yes ☐ unknown ☐

If yes,
please enter:

starting date ☐☐☐☐☐☐ stopping date ☐☐☐☐☐☐

Brand name: _____

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

Comment: _____

If yes,
please enter:

starting date ☐☐☐☐☐☐ stopping date ☐☐☐☐☐☐

Brand name: _____

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

Comment: _____

Interview no. ☐☐☐☐☐☐☐☐

WEEK 8 (+/- 2 weeks)

THERAPY 3

4) Antibiotics no ☐ yes ☐ unknown ☐

If yes,

- Therapeutic use ☐ starting date ☐☐☐☐☐☐

- Prophylactic use ☐ starting date ☐☐☐☐☐☐

- Unknown indication ☐ starting date ☐☐☐☐☐☐

TRANSFER TO OTHER HOSPITAL OR DEPARTMENT FOR TREATMENT OF SCAR

no ☐ yes ☐

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