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

<i>R e</i>	g i S C A R
	Interview no.
PATII	ENT'S DATA
Initials of the patient	date of birth
Age	country of birth
Gender male	
female	
Death before interview	Participation agreed to by the patient
no	registry
yes	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 t	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 sym	ptoms				
Fever If yes,	no	yes	unknown			
date of onset		date of norm	alization*	highest temperatu	re (°C) method of	f measurement

^{*} if cured before admission

Interview no.	
date of normalization*	
date of normalization*	

SKIN SYMPTOMS				1	
Burning	no	yes	unknown	date of onset	date of normalization*
Pain					
Pruritus					
Exanthema If yes,					
- maculopapular / morbilliform					
- urticarial					
- confluent erythema					
- exfoliative dermatitis					
- other:(please specify)					
Specific lesions	no	yes	unknown		
If yes,					
- edematous erythema				date of onset	date of normalization*
- target-like lesions					
- pustules					
- purpura					
- infiltrated plaques					
- eczema-like lesions					
Blisters / erosions	no	yes	unknown	date of onset	
Nikolski's skin					
Facial edema					
Maximum of erythema (percentage related to the BSA)				date of maximum	
Maximum of detachment (percentage related to the BSA if blisters/	erosions	were seen)			
Resolution of erythema/	no	yes	unknown		

Specific lesions ≥ 15 days * if cured before admission

2012-12-20

Inte	rvie	ew r	10.	

MUCOSAL SYMPTOMS	no	yes	unknown		
If yes, please specify				date of onset	date of resolution*

^{*} if cured before admission

Inte	rvie	w r	10.	

ORGAN INVOLVEMENT 1

LIVER	no	yes	unknown				
If yes, please specify				date of	diagr	nosis	
- Jaundice	no	yes	unknown	date of	onset	t	
Is there a suspicion of excessive alcohol intake?	no	yes	unknown				
If yes, chronic		acute					
KIDNEY If yes, please specify	no	yes	unknown				
				date of	diagr	10515	
LUNG	no	yes	unknown				
If yes, please specify				date of	diagr	nosis	
DYSPNEA	no	yes	unknown	date of	onset	t	

Inte	rvie	ew r	10.	

ORGAN INVOLVEMENT 2

HEART / MUSCLES	no	yes	unknown	
If yes, please specify				date of diagnosis
GI-TRACT				
If yes, please specify				date of diagnosis
PALPABLE LYMPH NODES (>1cm, at least two sites)				date of diagnosis
NEUROLOGICAL SYSTEM				144 - 6 - 1144
- Headache				date of onset
- Paresis				
- other				
If yes, please specify				date of diagnosis
SORE THROAT				date of onset
OTHER ORGAN INVOLVEMENT				
If yes, please specify				date of diagnosis
If yes, please specify				date of diagnosis

Interview no.								

MEDICAL IMAGING AND BIOPSIES 1

Have the following investigations been done?

- X-ray chest	If yes,	no	yes	abnorma	unknown		date of performance
- Chest-CT	If yes,	no normal	yes	abnorma	unknown	please spec	date of performance
- Bronchial endosc	copy If yes,	no	yes	abnorma	unknown	please spec	date of performance
- ECG	If yes,	no normal	yes	abnorma	unknown	please spec	date of performance
- Echocardiogram	If yes,	no normal	yes	abnorma	unknown	please spec	date of performance
- Abdominal sonoş	graphy If yes,	no	yes	abnorma	unknown	please spec	date of performance

Interview no.							

MEDICAL IMAGING AND BIOPSIES 2

Have the following investigations been done?

- Gastrointest. endoscopy If yes,	no no normal	yes	unknown abnormal	date of performance
	no	yes	unknown	please specify date of performance
- Other imaging (CT/MR If yes,	I) normal		abnormal	
If yes,	normal	8	abnormal	please specify please specify
- Liver biopsy If yes,	no	yes	unknown	date of performance
	no	yes	unknown	please specify date of performance
- Kidney biopsy If yes,	normal		abnormal	
- Biopsy of other organ If yes,	no normal	yes	unknown abnormal	date of performance
- Puncture of other organ If yes,	no normal	yes	unknown abnormal	date of performance please specify

Interview no.							

BLOOD CELL COUNT - VALUES -

Date of sampling:						
Laboratory numbe	r:					
(ascending number t	or eac	h lab	or if ran	iges/units	are upda	ted)

	Value
	(numerical)
Leucocytes	
Neutrophils	
Eosinophils	
Basophils	
Lymphocytes	
Atyp. Lymphocytes	
Monocytes	
Platelets	
НВ	
Quick	
PTT	
Other 1.:	
Other 2.:	
Other 3.:	
Other 4.:	
Other 5.:	

Interview no.							

CLINIAL CHEMISTRY - VALUES -

Date of sampling:	
Laboratory number	r:
(ascending number f	for each lab or if ranges/units are updated)

	Value (numerical)
ALAT	
ASAT	
GGT	
AP	
LDH	
Bilirubin	
Lipase	
Amylase	
Creatinine	
Creatinine clearance	
Urea	
Proteinuria	
Hematuria	
Leucocyturia	
CK	
CK-MB	
Troponin	
CRP	
PH	
PO_2	
PCO ₂	
HCO ₃	
SaO ₂	
Base excess	
Other 1.:	
Other 2.:	
Other 3.:	
Other 4.:	
Other 5.:	

Interview no.							

BLOOD CELL COUNT - REFERENCE RANGES AND UNITS -

Laboratory number:				
(ascending number for e	each la	ab or if	ranges/unit	s are updated)

	Lower limit (numerical)	Upper limit (numerical)	Unit (text)
Leucocytes			
Neutrophils			
Eosinophils			
Basophils			
Lymphocytes			
Atyp. Lymphocytes			
Monocytes			
Platelets			
НВ			
Quick			
PTT			
Other 1.:			
Other 2.:			
Other 3.:			
Other 4.:			
Other 5.:			

Interview no.									

CLINIAL CHEMISTRY - REFERENCE RANGES AND UNITS -

Laboratory number:		
(ascending number for e	ach lab or if ranges/units are upda	ated)

	Lower limit	Upper limit	Unit
	(numerical)	(numerical)	(text)
ALAT			
ASAT			
GGT			
AP			
LDH			
Bilirubin			
Lipase			
Amylase			
Creatinine			
Creatinine clearance			
Urea			
Proteinuria			
Hematuria			
Leucocyturia			
CK			
CK-MB			
Troponin			
CRP			
PH			
PO_2			
PCO ₂			
HCO ₃			
SaO ₂			
Base excess			
Other 1.:			
Other 2.:			
Other 3.:			
Other 4.:			
Other 5.:			

Interview no.									

LABORATORY VALUES 1

Have the following laboratory examinations been done?

		n	y	u	If yes, please specify:				
					Date of sampling	Comments (result, method, titer, etc.)			
Blood culture	1								
	2								

		n	y	u	If yes, please specify:					
					Date of sampling	Suggesting recent infection/ re- activation	Comments (result, method, titer, etc.)			
Chlamydia	1									
	2									
Mycoplasma	1									
	2									
				Oth	er laboratory o		lease specify:			
					Date of sampling	Suggesting recent infection/ re-activation	Comments (result, method, titer, etc.)			
Other 1.:										
Other 2.:										
Other 3.:										
Other 4.:										
Other 5.:										

Interview no.										

LABORATORY VALUES 2

Have the following laboratory examinations been done?

		n	y	u	If yes, please specify:					
					Date of sampling	Suggesting recent infection/ re-activation	Comments (result, method, titer, etc.)			
HAV	1					activation				
	2									
HBV	1									
	2									
HCV	1									
	2									
EBV	1									
	2									
CMV	1									
	2									
HHV6	1									
	2									
Parvovirus B19	1									
	2									
ANA	1									
				Other	laboratory ex	aminations				
							lease specify:			
					Date of	Suggesting	Comments (result, method,			
					sampling	recent infection/	titer, etc.)			
						re-				
						activation				
Other 1.:										
Other 2.:										
Other 3.:										
Other 4.:										
Other 5.:										

Interview no.									

FOR ALL CASES

FURTHER INFORMATION FOR CASE VALIDATION

Photographs		no	yes	unknown	date of first occurrence
Biopsy					
Diagnosis by a derm	natologist				
If yes, please speci	fy:				
Further photographs	/ biopsies and	comme	<u>nts</u> :		
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 h	erpes labialis o	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 ge	enital herpes?				
	no	yes	unknown	date of last eruption	

*if cured before admission

Interview no.										

SYMPTOMS / EVENTS WITHIN 1 MONTH BEFORE THE RECENT SKIN REACTION

Infections If yes,	no	yes	unknown									
n yes,				dat	e of c	onset	dat	e of	norr	naliz	ation	*
- 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 cu	ired l	befor	e adı	nissior
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?

Severe liver disorders	no	yes	unknown	year	of event
If yes, (please specify)					
Severe kidney disorders	no	yes	unknown	year	of event
If yes, (please specify)					
Rheumatic / collagen-vascular disease	e no	yes	unknown		
If yes,					
- rheumatoid polyarthritis				year	of event
- systemic lupus erythematosus					
- other:					
If yes,					
(please specify)		*****			
Was a first-degree family member diagnosed with any rheumatic/ collagen-vascular disease?	no	yes	unknown		
Inflammatory bowel disease	no	yes	unknown		
- Colitis ulcerosa				year	of event
- Crohn's disease					
Psoriasis	no	yes	unknown	year	of event
- Pustular psoriasis, generalized					
Was a first-degree family member diagnosed with psoriasis?	no	yes	unknown		
Convulsive disorder / epilepsy	no	yes	unknown	year	of event

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?

Malignant diseases / cancer	no	yes	unknown	
If yes, please specify:				year of event
If yes, please specify:				
HAVE YOU HAD ANY RADIOT	HERAPY I	RECENT	ΓLY?	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 specify)
- brain tumor				(please specify)
- other reason:				d 1 2/
(please specify))	_		
HAVE YOU IN THE PAST HAD	ANY TRA	NSPLAN		
Transplantation	no	yes	unknown	year of transplantation
If yes,				
- Stem cell				
- other:				
HAVE YOU IN THE PAST HAD	ANY SCAI			_
SCAR	no	yes	unknown	year of event
If yes, please specify:(please	specify)			

Interview no											

If yes, please specify:

unknown

		-	12 -	Intervi	ew no
medication sheet noof					
MEDICATION HIST	ORY WIT	HIN 1 M	IONTH BEFORE I	HOSPITALIZATI	
date of admission			drug use	no yes	unknown
			drug usc	, L	
Drug	Type of	Dose	Begin of intake	End of intake	Frequency
	application		day month year	day month year	
Indication					
marcation					
previous intake	no	yes	unknown		
	no	Lios	unknown	If yes, please specify:	
If yes, any adverse reaction	no	yes	ulikilowii	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		
previous intake					
If yes, any adverse reaction	no	yes	unknown	If yes, please specify:	
ir yes, any adverse reaction					
Descri	Tomoof	Daza	Danin of intoles	End of intake	E
Drug	Type of application	Dose	Begin of intake		Frequency
			day month year	day month year	
Indication					
	no	yes	unknown		

previous intake

If yes, any adverse reaction

	In	terv	iew	no	

		-	13 -	Intervi	ew no
medication sheet noof					
MEDICATION HIST date of admission	ORY WIT	HIN 1 M	ONTH BEFORE I	no yes	ON unknown
Drug Indication	Type of application	Dose	Begin of intake day month year	End of intake day month year	Frequency
previous intake	no no	yes yes	unknown unknown	If yes, please specify:	
If yes, any adverse reaction					
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					
	no	yes	unknown		

yes

unknown

If yes, please specify:

previous intake

If yes, any adverse reaction

medication sheet noof		-	14 -	Intervi	ew no
MEDICATION HIST date of admission	ORY WIT	HIN 1 M	ONTH BEFORE I	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 If yes, any adverse reaction	no no	yes yes	unknown 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 If yes, any adverse reaction	no no	yes yes	unknown unknown	If yes, please specify:	
Drug	Type of application	Dose	Begin of intake	End of intake	Frequency
Indication			day month year	day month year	
	no	yes	unknown		

If yes, please specify:

unknown

previous intake

If yes, any adverse reaction

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 equation:			

DI	SCI	HΔ	R	GE	SE	IFF	T

Interview no.									

Discharge diagnoses					
1.					
2					
3					
4					
5					
Results of the present admission	n				
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	c means	was the d	iagnosis reach	ned:	
serology					
isolation					
x-ray					
PCR					

unknown

Interview no.									

MAIN SOURCE OF INFORMATION

) Clinical pattern of the reaction	on			
* Were the skin lesions seen by the investigator in acute stage?	he	no	yes	unknowr
If not, please provide the sour (e.g., family physician,		family member)		
2) Medication history				
* just patient				
* just other source		If yes, plea	se 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 Death	
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 HOSPI	ITAL	hospital no.]	date of admission	
1. Burn unit					
2. Dept. of dermatolo	gy				
3. Intensive care unit					
4. Pediatric departme	nt				
5. Internal medicine					
6. Other:					
(p	lease specify)				
SYSTEMIC THERA	APY				
1) Corticosteroids	no	yes	unknown		
If yes, please enter:	starting date		stopping date		
Brand name/drug:					
Dosage:	App (if varying please provide minimum and ma	_	.o. i.v.		
Comment:					
2) IVIG	no	yes	unknown		
If yes, please enter:	starting date		stopping date		
Brand name/drug:					
Dosage:	(if varying please provide minimum and ma	ximum)			
Comment:					

Interview no.						

THERAPY 2

3) Ciclosporin	no yes	unknown
If yes, please enter:	starting date	stopping date
Brand name/drug:		
Dosage:	f varying please provide minimum and maximum)	
Comment:		
4) Other systemic t	reatments no yes	unknown
If yes, please enter:	starting date	stopping date
Brand name/drug:		
Dosage: Comment:	Application: (if varying please provide minimum and maximum)	p.o. i.v.
Comment.		
If yes, please enter: Brand name/drug:	starting date	stopping date
5		
Dosage:	Application: (if varying please provide minimum and maximum)	p.o. i.v.
Comment:		

THERAPY 3

unknown

starting da	ate	
tarting da	ate	
date of di		

TRANSFER TO OTHER HOSPITAL OR DEPARTMENT FOR TREATMENT OF SCAR

no		yes

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

- did the patient developed septicaemia?

5) Antibiotics

If yes,