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

Case Record Form

Interview no.							

HSS/DRESS	
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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 GERMANY

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

RegiSCAR

	Interview no.
PATIENT'S D	ATA
Initials of the patient	date of birth
Age	country of birth
Gender male	
female	
Death before interview no	Participation agreed to by the patient registry
yes	cohort study
	genetic study

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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 no yes	the reporting / treating hospital:	
unknown		
If yes, first hospital:	hospital no.	date of admission
Retrospective assessment		
no		
yes		
Development of skin reaction		
prior to admission		
during inhospital stay		

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DIAGNOSES AND CLINICAL COURSE

Admission diagnoses						
1)						
2)						
3)						
Date	Clinical sympto	oms				
				-		
				-		
	no	VAS	unknown			
Fever	no	yes	ulikilowii			
If yes,					(0.5)	
date of onset		date of norm	alization*	highest temp	perature (°C)	

* if cured before admission

					Interview no.
FOR	CA	SES OF	HSS /	DRESS ONLY	
SKIN SYMPTOMS		SES OF			
Burning, pain	no	yes	unknown	date of onset	date of normalization
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 sign					
					information from
Maximum of erythema (percentage related to the BSA)				date of maximum	investigator/photos chart
Maximum of detachment (percentage related to the BSA) (if blisters/erosions were seen)					
Resolution of erythema/ specific lesions ≥ 15 days	no	yes	unknown	date of resolution	
Facial edema	no	yes	unknown	date of onset	

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MUCOSAL SYMPTOMS	no	yes	unknown		
If yes, please specify:				date of onset	date of normalization

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ORGAN INVOLVEMENT 1

LIVER	no	yes	unknown	
If yes, please specify:				date of diagnosis
- Jaundice	no	yes	unknown	date of onset
Is there a suspicion of excess alcohol intake?	ive	no	yes unknown	
If yes,	chronic		acute	
KIDNEY If yes, please specify:	no	yes	unknown	date of diagnosis
LUNG If yes, please specify:	no	yes	unknown	date of diagnosis
DYSPNEA	no	yes	unknown	date of onset

Interview no.									

ORGAN INVOLVEMENT 2

HEART / MUSCLES	no	yes	unknown	
If yes, please specify:				date of diagnosis
- Chest pain				date of onset
- Palpitations				
- Muscular pain or weakness				
GI-TRACT				
If yes, please specify:				date of diagnosis
- Abdominal pain				date of onset
- Diarrhea				
- Dysphagia				
PALPABLE LYMPH NODES (>1cm, at least two sites)				date of diagnosis
NEUROLOGICAL SYSTEM				
- Headache				date of onset
- Paresis				
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?

	no		yes	unknown		date of perf	ormance
 X-ray chest 							
Ιf	yes,	n <u>orm</u> al	ab <u>norr</u>	mal			
	<i>y</i> c 5,	normar					
					please sp	pecify	
CI CT	no		yes	unknown		date of perf	ormance
- Chest-CT							
If	yes,	normal	abnorr	nal			
					please sp		
					piease sp	ectry	
	no		yes	unknown		date of perf	ormance
- Bronchial endoscop	У						
If	yes,	normal	ab <u>norr</u>	nal			
					please sp	pecify	
	no		yes	unknown		date of perf	ormance
- ECG							
Τf	e yes,	n <u>orm</u> al	ab <u>norr</u>	mal			
11	yes,	normai	aution				
					please sp	pecify	
	no		yes	unknown		date of perf	ormance
- Echocardiogram			700			date of peri	omanee
		,					
II	yes,	normal	abnorr	nai			
					please sp	pecify	
			Was .	unlenous		data of	
- Abdominal sonograp	no nhv		yes	unknown		date of perf	ormance
If	yes,	normal	abnorr	nal			
					please sp	pecify	
					-		

Interview no.								

MEDICAL IMAGING AND BIOPSIES 2

Have the following investigations been done?

	no		yes	unknown	date of performance	;
- Gastrointest. endoscopy						
If yes,		normal	abno	ormal	please specify	_
- Other imaging (CT/MRI) If yes,	no	normal	yes abno	unknown ormal please speci	date of performance	;
If yes,		normal	abno	ormalplease speci	date of performance	
- Liver biopsy If yes,	no	normal	yes abno	unknown Drmal	date of performance	
- Kidney biopsy If yes,	no	normal	yes abno	unknown Drmal	date of performance	:]
- Biopsy of other organ If yes,	no	normal	yes abno	unknown Drmal	date of performance	-
- Puncture of other organ If yes,	no	normal	yes abno	unknown Drmal	date of performance	:

Interview no.							

BLOOD CELL COUNT

Date of sampling:		
Laboratory numbe	r:	
(ascending number f	for each lab, only if first entry or the lab changed, lower and upper limits must be entere	d)

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

After saving the data you will be asked, whether you want to complete a further e-form.

Interview no.								

CLINICAL CHEMISTRY

Date of sampling:	
Laboratory number:	
(ascending number for each	a lab, only if first entry or the lab changed, lower and upper limits must be entered)

	Value (numerical)	Lower limit (numerical)	Upper limit (numerical)	Unit (text)
ALAT	(numerical)	(numerical)	(numericus)	(text)
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.:				

After saving the data you will be asked, whether you want to complete a further e-form.

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LABORATORY VALUES 1

Have the following laboratory examinations been done?

		n	y	u		If v	ves, please specify:		
			,						
					Date of samp	oling	Comments (result, method, titer, etc.)		
Blood culture	1								
	2								
				•		<u> </u>			
		n	y	u		If y	ves, please specify:		
					Date of Sampling	Suggestin recent infection			
Chlamydia	1								
	2								
Mycoplasma	1								
	2								
			0	ther l	aboratory exar	ninations			
						If y	ves, please specify:		
					Date of Sampling	Suggestin recent infection			
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		please specify:	
					Date of Sampling	Suggesting recent infection	Comments (result, method, titer, etc.)
HAV	1						
	2						
HBV	1						
	2						
HCV	1						
	2						
EBV	1						
	2						
CMV	1						
	2						
HHV6	1						
	2						
Parvovirus B19	1						
	2						
ANA							
			0	ther l	aboratory exai	minations	
							please specify:
					Date of Sampling	Suggesting recent infection	Comments (result, method, titer, etc.)
Other 1.:							
Other 2.:							
Other 3.:							
Other 4.:							
Other 5.:							

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FOR ALL CASES

FURTHER INFORMATION FOR CASE VALIDATION

Photographs	no	yes	unknown	date of first occurrence
Biopsy				
Diagnosis by a dermatologist				
If yes, please specify:				
Further photographs:				
Date Notes				
SCORTEN-PARAMETERS (wi	thin 3 da	ıys after	admission)
- Urea > 10 mmol/l		no	yes	not done
If yes, highest value: mmo	1/1			
- Glycemia > 14 mmol/l				
If yes, highest value: mmo	1/1			
- Bicarbonate < 20 mmol/l	1.0			
If yes, lowest value: mmol	1/1			
- Heart rate > 120 /min				

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	s labialis o	r fever b	listers?		
	no	yes	unknown	date of last eruption	
Herpes genitalis	no	yes	unknown	date of onset	date of normalization*
Do you have recurrent genita	l 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	no	yes	unknown		
If yes,				date of onset	date of normalization*
- influenza / influenza-like illness				date of offset	
- rhinopharyngitis / common cold					
- tonsillitis					
- sinusitis					
- acute otitis					
- acute bronchitis					
- pneumonia					
- acute gastroenteritis					
- acute cystitis					
* bacterial infection proven					
* prior cystitis					
- other infections					
(please specify)				date of onset	date of normalization*
(please specify)					
HIV-status					
HIV	no	yes	unknown		
AIDS					
If yes, most recent CD4 count per μ1:					

*if cured before admission

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HAVE YOU IN THE PAST HAD ANY OF THE FOLLOWING DISEASES?

	no	yes	unknown	year of event
- Atopic dermatitis / childhood eczema				
- Psoriasis				
- SCAR				
If yes, please specify:				
Severe liver disorders?	no	yes	unknown	
If yes,				
(please specify)				
	no	yes	unknown	
Severe kidney disorders?				
If yes,				
(please specify)				
Rheumatic / autoimmune diseases?	no	yes	unknown	
If yes,				
- rheumatoid arthritis				
- systemic lupus erythematosus				
- other:				
If yes,				
(please specify)				

				Interview no.
Other diseases				
	no	yes	unknown	year of event
- Diabetes mellitus				
- Convulsive disorder / epilepsy				
- Allergic rhinitis				
- Asthma				
- Inflammatory bowel disease				
* Colitis ulcerosa				
* Crohn's disease				
- Malignant diseases / cancer				
If yes, please specify:				
If yes, please specify:				
Radiotherapy	no	VAC	unknown	date of most recent therapy
Have you ever had x-ray or radiotherapy? (not UV-radiation)	no	yes		recent therapy
If yes, for what indication?				
- lymphoma				(-1
				(please specify)
- brain tumor				(please specify)
- other reason:				
(please specify)				

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		- 1	2 -	Intervi	ew no.
medication sheet no of					
	STORY	WITHIN 1	MONTH BEFORE I	HOSPITALIZATION	
date of admission				no drug use	
Drug	Dose	Type of application	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	Dose	Type of application	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:	
Drug	Dose	Type of application	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:	

		- 1	13 -	Intervi	ew no.
medication sheet no of					
	STORY	WITHIN 1	MONTH BEFORE H	IOSPITALIZATION	
date of admission				no drug use	
				no drug use	
Drug	Dose	Type of	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:	
Drug	Dose	Type of	Begin of intake	End of intake	Frequency
		application	day month year	day month year	
Indication					
marcation					
previous intake		no yes	unknown		
If yes, any adverse reaction		no yes	unknown	If yes, please specify:	
n yes, any adverse reaction					
Drug	Dose	Type of	Begin of intake	End of intake	Frequency
		application	day month year	day month year	
Indication					
	•	no yes	unknown	•	
previous intake					
		no yes	unknown	If yes, please specify:	
If yes, any adverse reaction					

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medication sheet no of							
	STORY	WITHIN 1	MONTH BEFORE	HOSPITALIZATION			
date of admission		***************************************		no drug use			
Drug	Dose	Type of application	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	Dose	Type of application	Begin of intake day month year	End of intake day month year	Frequency		
			The month year				
Indication							
previous intake		no yes no yes	unknown unknown	If yes, please specify:			
If yes, any adverse reaction							
Drug	Dose	Type of application	Begin of intake	End of intake	Frequency		
		аррисацон	day month year	day month year			
Indication							
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 an adverse reaction to drugs?

	no	yes	unknown
If yes,			
Drug:			
Type of reaction:			
Drug:			
Type of reaction:			
Drug:			
Type of reaction:			
Drug:			
Type of reaction:			
Drug:			
Type of reaction:			

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Interview no.						

h	ospi	ital	no.

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	o yes	unknown	date of diagnosis	
If yes, criteria:				
serology				
isolation				
x-ray				

Inte	ervi	ew i	no.	

MAIN SOURCE OF INFORMATION

1) Clinical pattern of the reaction				
* Were the skin lesions seen by the investigator in acute stage?		no	yes	unknown
If not, please provide the source (e.g., family physician, derm	natologist, nu	rse, family mem	ber)	
2) Medication history				
* just patient				
* just other source		If yes , pleas	e specify:	
* both		If yes, pleas	e specify:	
UNIT OF TREATMENT				
1. Burn unit				
2. Dept. of dermatology				
3. Intensive care unit				
4. Pediatric department				
5. Internal medicine				
6. Other:				
(please specify)				

Interview no.								

ADDITIONAL REMARKS

Please use the fields below to note important additional information.

Please stick to the predefined topics and avoid redundancy:

For cases a	nd controls:
	Here you can specify additional information regarding ethnic origin:
Only for ca	ises:
Here you	can specify if patient died after discharge before the follow-up or blood sampling Please specify date of death correspondingly:
Here y	you can specify any other reason why follow-up investigations/blood sampling could not be done:
	Further relevant remarks (if agreed upon by Data Center):

THER	AP	Y	1
	Δ	_	

Interview no.						
		_				

TREATING HOSPITAL		hospital no.	date of admission		
1. Burn uni	t				
2. Dept. of	dermatology				
3. Intensive	care unit				
4. Pediatric	department				
5. Internal r	nedicine				
6. Other:					
	(please specify)				
SYSTEMIC 1) Corticos If yes,	C THERAPY steroids	no yes starting date sto	unknown opping date		
please ente	er:	starting date ste	pping 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.		

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2) IVIG			no	yes	unknown	
If yes, please enter	dates:		starting c	late	stop	ping date
Day 1	Brand name:					
	Dosage:					
Day 2	Brand name:					
	Dosage:					
Day 3	Brand name:					
	Dosage:					
Day 4	Brand name:					
	Dosage:					
3) Other syst	emic treatment	s	no	ye	s ı	ınknown
If yes, please enter:			starting c	late	stop	ping date
Brand nam	ne:					
Dosage:		App	lication:	p.o.	i.v.	
Comment:						
If yes, please enter:			starting d	late	stop	ping date
Brand nam	ne:					
Dosage:		App	lication:	p.o.	i.v.	
Comment:						

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	Т	HERA	PY 3	
4) Antibiotics	no	yes	unknown	
If yes,				
- Therapeutic use				starting date
- Prophylactic use				starting date
- Unknown indication				starting date
FRANSFER TO OTHER HOSPIT	TAL OR DI	E PARTM	ENT FOR TREAT	TMENT OF SCAR
	no		yes	

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