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

RegiSCAR
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## **Case Record Form**

Interview no.							

SJS/TEN	
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# EUROPEAN REGISTRY OF SEVERE CUTANEOUS ADVERSE REACTIONS TO DRUGS AND COLLECTION OF BIOLOGICAL SAMPLES

# RegiSCAR

	Interview no.
PATIENT'S DA	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

Interview no.						

## **HOSPITAL DATA**

Reporting nospital / 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	o 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		

Interview no.						

# DIAGNOSES AND CLINICAL COURSE

Admission diagnoses					
1)					
2)					
3)					
Date	Clinical sympto	oms			
	- <u></u>				
Fever	no	yes	unknown		
If yes,		_			
date of onset		date of norm	alization*	highest temperatur	re (°C)

\* if cured before admission

<b>FOR</b>	<b>CASES</b>	<b>OF</b>	SJS	/ TEN	<b>ONL</b>	Y
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	Inte	rvie	ew r	10.	

	SKIN	SYMP	TOMS
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Burning, pain	no	yes	unknown	date of onset	date of normaliz	zation*
Pruritus						
Erythema, exanthema						
If yes,						
- maculopapular / morbilliform						
- urticarial						
- large diffuse erythema (withou	it spots)					
- other:(please specify)						
Target lesions	no	yes	unknown	date of onset		
If yes,						
- typical targets					distribution:	
- atypical targets raised					mainly limbs	
- atypical targets flat					widespread	
- spots					other:	
- type of target lesions unknown					(please specify)	
Blisters / erosions	no	yes	unknown	date of onset		
Nikolski's sign						
Epidermal sheets > 5 cm						
Localization of first blister / erosio	n:					
Maximum of erythema (percentage related to the BSA)				date of maximu	m	
Maximum of detachment (percentage related to the BSA)					*:6 6	

<sup>\*</sup> if cured before admission

Interview no.								

#### FOR CASES OF SJS / TEN ONLY

# **MUCOSAL SYMPTOMS** no unknown **Eyes** If yes, date of onset date of normalization\* - stinging, burning - redness - severe conjunctivitis / blepharitis date of diagnosis - diagnosis by an ophthalmologist If yes, please specify: \_\_ unknown Lips If yes, date of onset date of normalization\* - burning, pain - swelling, edema - erosions, hemorrhagic crusts unknown Oral mucosa If yes, date of onset date of normalization\* - burning, pain

\* if cured before admission

- redness, spots

- erosions, hemorrhagic crusts

Interview no.								

# FOR CASES OF SJS / TEN ONLY

Genital mucosa	no	yes	unknown		
If yes,				1	1. 6 1
- burning, pain				date of onset	date of normalization*
- redness, spots					
- erosions, hemorrhagic crusts					
Erosions of other mucosa	no	yes	unknown	date of onset	date of normalization*
If ves. please specify:					

\*if cured before admission

Inte	rvie	w r	10.	

## 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 (w	rithin 3 d	lays afteı	· admission	)
- Urea > 10 mmol/l  If yes, highest value: mmo	ol/I	no	yes	not done
- Glycemia > 14 mmol/l  If yes, highest value: mmo	ol/l			
- Bicarbonate < 20 mmol/l  If yes, lowest value: mmo	ol/l			
- 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	data of normalization*
- influenza / influenza-like illness				date of onset	date of normalization*
- 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 μl:					

\*if cured before admission

Interview no.									

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

- Atopic dermatitis / childhood eczema	no	yes	unknown	year of event
- Psoriasis				
- SCAR				
If yes, please specify:				
Severe liver disorders?	no	yes	unknown	
If yes,				
(please specify)				
(preuse speerry)				
	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				
- Diabetes mellitus	no	yes	unknown	year of event
Diacetes memeras				
- 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:				
n yes, please specify:			······	
Radiotherapy				date of most
Have you ever had x-ray	no	yes	unknown	recent therapy
or radiotherapy? (not UV-radiation)				
If yes, for what indication?				
- lymphoma				
				(please specify)
- brain tumor				(please specify)
- other reason:				(produce openity)
- OHIEL TEASOIL				
(please specify)				

- 12 -

		12 -	Intervi	ew no.	
medication sheet no of					
	STORY	WITHIN 1	MONTH BEFORE I	HOSPITALIZATION	
date of admission				no drug use	
				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	Begin of intake	End of intake	Frequency
		application	day month year	day month year	
Indication					
previous intake		no yes	unknown		
pre vious mune				<b>If</b>	
If yes, any adverse reaction		no yes	unknown	If yes, please specify:	
					<del></del>
Drug	Dose	Type of application	Begin of intake	End of intake	Frequency
			day month year	day month year	
Indication					
previous intake		no yes	unknown		
previous illiane				TC	
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	<b>IOSPITALIZATION</b>	
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					

		- 1	4 -	Intervi	ew no.
medication sheet no of					
MEDICATION HIS	STORY	WITHIN 1 N	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	End of intake	Frequency
			day month year	day month year	
Indication					
previous intake  If yes, any adverse reaction		no yes no yes	unknown unknown	If yes, please specify:	
Drug	Dose	Type of application	Begin of intake day month year	End of intake day month year	Frequency
Indication					
moleculon					
previous intake		no yes	unknown		
If yes, any adverse reaction		no yes	unknown	If yes, please specify:	

Interview no.							

# Have you ever had an adverse reaction to drugs?

	no	yes	unknown
If yes,			
Drug:			
D146			
_			
Type of reaction:	 		
Deno			
Drug:			
Type of reaction:	 		
Dave			
Drug:			
Type of reaction:	 		
D			
Drug:	 		
Type of reaction:	 		
D			
Drug:	 		
Type of reaction:			

D	IS	$\mathbf{CH}A$	R (	${\bf FE}$	SH	$\mathbf{E}\mathbf{E}$	T

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	no 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, please	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 and	controls:
Н	ere you can specify additional information regarding ethnic origin:
Only for cases	
Here you can	specify if patient died after discharge before the follow-up or blood sampling Please specify date of death correspondingly:
Here 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):

<b>THER</b>	AP	Y	1
	$\Delta$	_	

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	medicine	
6. Other:		
	(please specify)	
1) Corticos	C THERAPY steroids	no yes unknown
If yes, please ente	er:	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.

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Interview no.							

2) IVIG		no	yes un	known
If yes, please enter of	dates:	start	ing 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 syst	emic treatments	start	no yes ing date	unknown stopping date
please enter:				
Brand nam	e:			
Dosage:		Application:	p.o.	i.v.
Comment:				
If yes, please enter:		start	ing date	stopping date
Brand nam	e:			
Dosage:		Application:	p.o.	i.v.
Comment:				

						Interview no.				
	TH	(ERAP	Y 3							
4) Antibiotics If yes,	no	yes	unknown							
- Therapeutic use				sta	arting d	late				
- Prophylactic use				sta	arting d	late				
- Unknown indication				sta	arting d	late				
TRANSFER TO OTHER HOSPITA	AL OR DEP	ARTME	NT FOR TREATMENT	OF SC	CAR					
	no		yes							

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