Validation of ScleroID

COUNTRY_____ **Patient number /__/__/**

BASELINE – PATIENT CRF

Today's Date: Day /__/__/ Month /__/__/ Year 20/__/__/

B1. Impact and weighting of disease

We want you to indicate how much your systemic sclerosis (scleroderma) impacts your health in the following selected health dimensions, shown below.

Please distribute 100 points between the dimensions according to their impact; the sum should be 100.
Please read all dimensions before starting to distribute your points.

You can spend your points in sets of 5. Give more points to dimensions which have important impact and less to dimensions that are not so important. You do not have to spend points in every area. You cannot spend more than 100 points.
Please take into account your whole disease history, not only how you feel today, when distributing the points.

In this table, you have to distribute your 100 points between 10 domains of health:.

Domain/dimension	POINTS
Raynaud's Phenomenon	I__I__I
Hand function	I__I__I
Pain	I__I__I
Fatigue *(being tired physically, but also mental fatigue, lack of energy)*	I__I__I
Upper gastrointestinal tract symptoms *(e.g. swallowing difficulties, reflux, vomiting)*	I__I__I
Lower gastrointestinal tract symptoms *(e.g. bloating, diarrhea, constipation, anal incontinence)*	I__I__I
Limitations of life choices and activities *(e.g. social life, personal care, work)*	I__I__I
Body mobility	I__I__I
Breathlessness	I__I__I
Digital ulcers	I__I__I
TOTAL POINTS: Remember must add up to 100 points	100

Validation of ScleroID

COUNTRY_____ **Patient number /__/__/**

B2. The EULAR Scleroderma Impact of Disease Score (ScleroID)

How much have the different aspects of systemic sclerosis affected you during the last week? Please mark your responses on the scale by choosing the appropriate number for each of the following dimensions:

Raynaud's phenomenon:

Circle the number that best describes the severity of your Raynaud's phenomenon during the last week:

None	0	1	2	3	4	5	6	7	8	9	10	Extreme

Hand function:

Circle the number that best describes your hand function limitations due to your systemic sclerosis during the last week:

No limitation	0	1	2	3	4	5	6	7	8	9	10	Extreme limitation

Upper gastrointestinal tract symptoms (e.g. swallowing difficulties, reflux, vomiting):

Circle the number that best describes the severity of your upper gastrointestinal tract symptoms due to your systemic sclerosis during the last week:

None	0	1	2	3	4	5	6	7	8	9	10	Extreme

Pain:

Circle the number that best describes the pain you felt due to your systemic sclerosis during the last week:

None	0	1	2	3	4	5	6	7	8	9	10	Extreme

Fatigue:

Circle the number that best describes the impact of overall fatigue due to your systemic sclerosis during the last week:

None	0	1	2	3	4	5	6	7	8	9	10	Extreme

Lower gastrointestinal tract symptoms (e.g. bloating, diarrhea, constipation, anal incontinence):

Circle the number that best describes the severity of lower gastrointestinal tract symptoms during the last week:

None	0	1	2	3	4	5	6	7	8	9	10	Extreme

Limitations of life choices and activities (e.g. social life, personal care, work):

Circle the number that best describes how severe the limitations of life choices and activities due to your systemic sclerosis were during the last week:

No	0	1	2	3	4	5	6	7	8	9	10	Extreme

Validation of ScleroID

COUNTRY_____ **Patient number /__/__/**

Body mobility:

Circle the number that best describes how much your body mobility was affected due to your systemic sclerosis during the last week:

Not affected	0	1	2	3	4	5	6	7	8	9	10	Extremely affected

Breathlessness:

Circle the number that best describes how severe your breathlessness due to systemic sclerosis was during the last week:

None	0	1	2	3	4	5	6	7	8	9	10	Extreme

Digital ulcers:

Circle the number that best describes how much your digital ulcers affected you overall during the last week:

None	0	1	2	3	4	5	6	7	8	9	10	Extreme

B3. Are you currently …. ?

- Working full-time of part-time (employed for wages) ☐
- A student ☐
- Retired ☐
- Unable to work/disabled ☐

B4. What is the highest level of education you completed so far?

- No schooling ☐
- Elementary/primary school ☐
- High school/middle school **without** university entrance qualification ☐
- High school/middle school **with** university entrance qualification ☐
- College/university **without** degree ☐
- College/university **with** degree – Bachelor (or equivalent) ☐
- College/university **with** degree – Master (or equivalent) ☐
- Doctorate degree ☐
- Trade/technical/vocational training ☐

Validation of ScleroID

COUNTRY_____ **Patient number /__/__/**

B5. Think about all the ways in which the systemic sclerosis has affected you during the last week, how would you consider this state? (Mark "**X**" in only one box below)

❑ Very good

❑ Good

❑ Acceptable

❑ Bad

❑ Very bad

B6. Think about all the ways your systemic sclerosis has affected you during the last week.

Compared to 1 week ago, how has the overall state of your disease been during the last week? (Mark "**X**" in only one box below)

☐ Much improved

☐ Moderately improved

☐ Stable (mostly unchanged)

☐ Moderately worsened

☐ Much worsened

B7. Global assessment

Considering **all the ways your systemic sclerosis** has affected you during the last week, circle the number that best describes how you have been doing:

Very good	0	1	2	3	4	5	6	7	8	9	10	Very bad

Validation of ScleroID

COUNTRY_____ **Patient number /__/__/**

B8. We are interested in learning how your illness affects your ability to function in daily life. Please check (X) the one best answer which best describes your usual abilities OVER THE PAST WEEK:

	Without ANY Difficulty(0)	With SOME Difficulty(1)	With MUCH Difficulty(2)	UNABLE To Do(3)
DRESSING & GROOMING				
Are you able to:				
- Dress yourself, including tying shoelaces and doing buttons?	_____	_____	_____	_____
- Shampoo your hair?	_____	_____	_____	_____
ARISING				
Are you able to:				
- Stand up from a straight chair?	_____	_____	_____	_____
- Get in and out of bed?	_____	_____	_____	_____
EATING				
Are you able to:				
- Cut your meat?	_____	_____	_____	_____
- Lift a full cup or glass to your mouth?	_____	_____	_____	_____
- Open a new milk carton?	_____	_____	_____	_____
WALKING				
Are you able to:				
- Walk outdoors on flat ground?	_____	_____	_____	_____
- Climb up five steps?	_____	_____	_____	_____

Please check any AIDS OR DEVICES that you usually use for any of these activities:

_____ Cane
_____ Walker
_____ Crutches
_____ Wheelchair
_____ Devices used for dressing (button hook, zipper pull, long-handled shoe horn, etc.)
_____ Built up or special utensils
_____ Special or built up chair
_____ Other (Specify: _____)

Please check any categories for which you usually need HELP FROM ANOTHER PERSON:

_____ Dressing and Grooming
_____ Arising
_____ Eating
_____ Walking

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COUNTRY_____ **Patient number /__/__/**

Please check the response which best describes your usual abilities OVER THE PAST WEEK:

	Without ANY Difficulty(0)	With SOME Difficulty(1)	With MUCH Difficulty(2)	UNABLE To Do(3)
HYGIENE				
Are you able to:				
- Wash and dry your body?	_____	_____	_____	_____
- Take a tub bath?	_____	_____	_____	_____
- Get on and off the toilet?	_____	_____	_____	_____
REACH				
Are you able to:				
- Reach and get down a 5 pound object (such as a bag of sugar) from just above your head?	_____	_____	_____	_____
- Bend down to pick up clothing from the floor?	_____	_____	_____	_____
GRIP				
Are you able to:				
- Open car doors?	_____	_____	_____	_____
- Open jars which have previously been opened?	_____	_____	_____	_____
- Turn faucets on and off?	_____	_____	_____	_____
ACTIVITIES				
Are you able to:				
- Run errands and shop?	_____	_____	_____	_____
- Get in and out of a car?	_____	_____	_____	_____
- Do chores such as vacuuming or yard work?	_____	_____	_____	_____

Please check any AIDS OR DEVICES that you usually use for any of these activities:

_____ Raised toilet seat
_____ Bathtub seat
_____ Jar opener (for jars previously opened)
_____ Other (Specify: _____)
_____ Bathtub bar
_____ Long-handled appliances for reach
_____ Long-handled appliances in bathroom

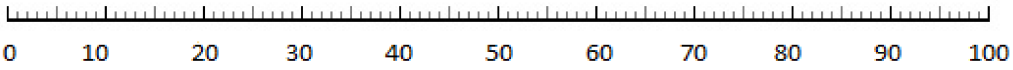
Please check any categories for which you usually need HELP FROM ANOTHER PERSON:

_____ Hygiene
_____ Reach
_____ Gripping and opening things
_____ Errands and chores

IN THE PAST WEEK, how much have your intestinal problems interfered with your daily activities?

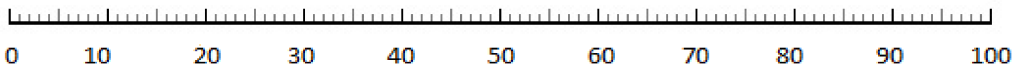
Validation of SclerolD

COUNTRY_____ **Patient number /__/__/**



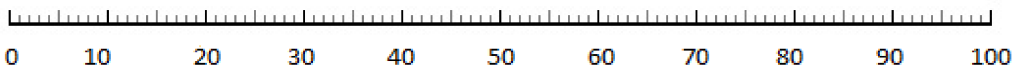
Does not interfere Very severe limitation

IN THE PAST WEEK, how much have your breathing problems interfered with your daily activities?



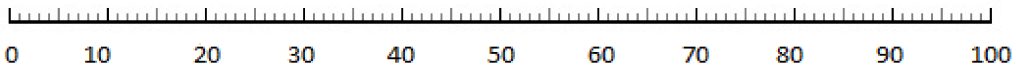
Do
es not interfere Very severe limitation

IN THE PAST WEEK, how much has Raynaud's interfered with your daily activities?



Does not interfere Very severe limitation

IN THE PAST WEEK, how much have your finger ulcers interfered with your daily activities?



Does not interfere Very severe limitation

B9. EQ-5D

By placing a tick in each group below, please indicate which statements best describe your own health state today.

Mobility

I have no problems in walking about ❒
I have some problems in walking about ❒
I am confined to bed ❒

Self-care

I have no problems with self-care ❒
I have some problems washing or dressing myself ❒
I am unable to wash or dress myself ❒

Usual activities (eg work, study, housework, family or leisure activities

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COUNTRY_____ **Patient number /__/__/**

I have no problems with performing my usual activities ❒
I have some problems with performing my usual activities ❒
I am unable to perform my usual activities ❒

Pain / discomfort
I have no pain or discomfort ❒
I have moderate pain or discomfort ❒
I have extreme pain or discomfort ❒

Anxiety / depression
I am not anxious or depressed ❒
I am moderately anxious or depressed ❒
I am extremely anxious or depressed ❒

B10. Overall assessment of health status (SF-36)

1. In general, would you say your health is:	
Excellent	1
Very good	2
Good	3
Fair	4
Poor	5
2. **Compared to one year ago**, how would your rate your health in general **now**?	
Much better now than one year ago	1
Somewhat better now than one year ago	2
About the same	3
Somewhat worse now than one year ago	4
Much worse now than one year ago	5

The following items are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

(Circle One Number on Each Line)

	Yes, Limited a Lot	Yes, Limited a Little	No, Not limited at All

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COUNTRY_____ **Patient number /__/__/**

3. **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	[1]	[2]	[3]
4. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	[1]	[2]	[3]
5. Lifting or carrying groceries	[1]	[2]	[3]
6. Climbing **several** flights of stairs	[1]	[2]	[3]
7. Climbing **one** flight of stairs	[1]	[2]	[3]
8. Bending, kneeling, or stooping	[1]	[2]	[3]
9. Walking **more than a mile**	[1]	[2]	[3]
10. Walking **several blocks**	[1]	[2]	[3]
11. Walking **one block**	[1]	[2]	[3]
12. Bathing or dressing yourself	[1]	[2]	[3]

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

(Circle One Number on Each Line)

	Yes	No
13. Cut down the amount of time you spent on work or other activities	1	2
14. **Accomplished less** than you would like	1	2
15. Were limited in the **kind** of work or other activities	1	2
16. Had **difficulty** performing the work or other activities (for example, it took extra effort)	1	2

During the **past 4 weeks,** have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems**(such as feeling depressed or anxious)? **(Circle One Number on Each Line)**

	Yes	No

Validation of ScleroID

COUNTRY_____ **Patient number /__/__/**

17. Cut down the **amount of time** you spent on work or other activities	1	2
18. **Accomplished less** than you would like	1	2
19. Didn't do work or other activities as **carefully** as usual	1	2

20. During the **past 4 weeks,** to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? **(Circle One Number)**

Not at all	1
Slightly	2
Moderately	3
Quite a bit	4
Extremely	5

21. How much **bodily** pain have you had during the **past 4 weeks**?

(Circle One Number)

None	1
Very mild	2
Mild	3
Moderate	4
Severe	5
Very severe	6

22. During the **past 4 weeks,** how much did **pain** interfere with your normal work (including both work outside the home and housework)? **(Circle One Number)**

Not at all	1
A little bit	2
Moderately	3

Validation of SclerolD

COUNTRY_____ **Patient number /__/__/**

Quite a bit 4

Extremely 5

These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling. **(Circle One Number on Each Line)**

How much of the time during the **past 4 weeks** . . .

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
23. Did you feel full of pep?	1	2	3	4	5	6
24. Have you been a very nervous person?	1	2	3	4	5	6
25. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
26. Have you felt calm and peaceful?	1	2	3	4	5	6
27. Did you have a lot of energy?	1	2	3	4	5	6
28. Have you felt downhearted and blue?	1	2	3	4	5	6
29. Did you feel worn out?	1	2	3	4	5	6
30. Have you been a happy person?	1	2	3	4	5	6
31. Did you feel tired?	1	2	3	4	5	6

32. During the **past 4 weeks,** how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)? **(Circle One Number)**

All of the time 1

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COUNTRY_____ **Patient number /__/__/**

Most of the time	2
Some of the time	3
A little of the time	4
None of the time	5

How TRUE or FALSE is each of the following statements for you.

(Circle One Number on Each Line)

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
33. I seem to get sick a little easier than other people	1	2	3	4	5
34. I am as healthy as anybody I know	1	2	3	4	5
35. I expect my health to get worse	1	2	3	4	5
36. My health is excellent	1	2	3	4	5

Thank you for filling in this questionnaire

Validation of ScleroID

COUNTRY_____ **Patient number /__/__/**

Baseline physician CRF

G1. Today's Date: Day /__/__/ Month /__/__/ Year 20/__/__/

G2. Do you confirm the main inclusion and exclusion criteria?

	Yes	No
G2.1. Age ≥ 18 years	❑	❑
G2.2. Able to understand the objectives of the study and the different questionnaires	❑	❑
G2.3. Written informed consent obtained	❑	❑
G2.4. Patient fulfilling the ACR/EULAR 2013 criteria for SSc	❑	❑
G2.5. No severe comorbidity NOT related to SSc (e.g. concomitant acute infectious disease, organ failure, recent acute cerebrovascular event, serious psychiatric or neurological disease)	❑	❑

Any negative answer results in the non-inclusion of the patient in the study.

G3. SSc characteristics

Please make sure that all necessary items of the EUSTAR dataset are evaluated and filled into the system (date of birth and diagnosis, clinical features, laboratory values, therapies etc.) AND that the patient fills in the necessary questionnaires/CRF.

Validation of ScleroID

COUNTRY_____ **Patient number /__/__/**

G4. Physician's assessment of SSc

G4.1. Physician's global assessment of SSc

Considering all the ways systemic sclerosis has affected your patient during the last week, circle the number that best describes how he/she has been doing:

Very good	0	1	2	3	4	5	6	7	8	9	10	Very bad

At the end of this visit, please check:

1. Is the patient eligible for the RELIABILITY ARM?

Eligibility criteria for the reliability arm:

- willingness to fill in the Reliability CRF after 7 +/- 3 days from the baseline visit (this can be sent per post, e-mail, or handed to the patient, as suitable)
- no major health change/intervention is medically forseeable/planed during the next 10 days

If the above conditions are fulfilled, please include the patient in the Reliability arm (see Reliability study - Physician CRF and Reliability Study – Patient CRF).

2. Is the patient eligible for the SENSITIVITY TO CHANGE ARM?

Eligibility criteria for the sensitivity to change arm:

- patients with active disease as defined by the physician
- feasible follow-up visits at 6 and 12 months (or at least one complete follow-up visit at 12 months), as medically required

If the above conditions are fulfilled, please include the patient in the Sensitivity to change arm.

3. IN ANY CASE, PLEASE CHECK PATIENT CRF and EUSTAR dataset FOR COMPLETENESS and fill in patient number!

THANK YOU!

Validation of SclerolD

COUNTRY_____ **Patient number /__/__/**

Validation of ScleroID

COUNTRY_____ **Patient number /__/__/**

RELIABILITY STUDY – PATIENT CRF

Please fill in this questionnaire 7+/-3 days after your last visit.

Today's Date: Day /__/__/ Month /__/__/ Year 20/__/__/

Please cross the correct answer:

S1. Since you last filled in this questionnaire, do you consider your systemic sclerosis to be stable? ..... yes ❑ no ❑

S2. Since you last filled in this questionnaire, has your treatment for your systemic sclerosis been changed? .... yes ❑ no ❑

S3. **Think about all the ways in which the systemic sclerosis has affected you during the last week, how would you consider this state?** (Mark "**X**" in only one box below)

❑ Very good
❑ Good
❑ Acceptable
❑ Bad
❑ Very bad

S4. Think about all the ways your systemic sclerosis has affected you during the last week.
Compared to 1 week ago, how has the overall state of your disease been during the last week? (Mark "**X**" in only one box below)

☐ Much improved
☐ Moderately improved
☐ Stable (mostly unchanged)
☐ Moderately worsened
☐ Much worsened

Validation of ScleroID

COUNTRY_____ **Patient number /__/__/**

S5. The EULAR Scleroderma Impact of Disease Score (ScleroID)

How much have the different aspects of systemic sclerosis affected you during the last week? Please mark your responses on the scale by choosing the appropriate number for each of the following dimensions:

Raynaud's phenomenon:

Circle the number that best describes the severity of your Raynaud's phenomenon during the last week:

None	0	1	2	3	4	5	6	7	8	9	10	Extreme

Hand function:

Circle the number that best describes your hand function limitations due to your systemic sclerosis during the last week:

No limitation	0	1	2	3	4	5	6	7	8	9	10	Extreme limitation

Upper gastrointestinal tract symptoms (e.g. swallowing difficulties, reflux, vomiting):

Circle the number that best describes the severity of your upper gastrointestinal tract symptoms due to your systemic sclerosis during the last week:

None	0	1	2	3	4	5	6	7	8	9	10	Extreme

Pain:

Circle the number that best describes the pain you felt due to your systemic sclerosis during the last week:

None	0	1	2	3	4	5	6	7	8	9	10	Extreme

Fatigue:

Circle the number that best describes the impact of overall fatigue due to your systemic sclerosis during the last week:

None	0	1	2	3	4	5	6	7	8	9	10	Extreme

Lower gastrointestinal tract symptoms (e.g. bloating, diarrhea, constipation, anal incontinence):

Circle the number that best describes the severity of lower gastrointestinal tract symptoms during the last week:

None	0	1	2	3	4	5	6	7	8	9	10	Extreme

Limitations of life choices and activities (e.g. social life, personal care, work):

Circle the number that best describes how severe the limitations of life choices and activities due to your systemic sclerosis were during the last week:

No	0	1	2	3	4	5	6	7	8	9	10	Extreme

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COUNTRY_____ **Patient number /__/__/**

Body mobility:

Circle the number that best describes how much your body mobility was affected due to your systemic sclerosis during the last week:

Not affected	0	1	2	3	4	5	6	7	8	9	10	Extremely affected

Breathlessness:

Circle the number that best describes how severe your breathlessness due to systemic sclerosis was during the last week:

None	0	1	2	3	4	5	6	7	8	9	10	Extreme

Digital ulcers:

Circle the number that best describes how much your digital ulcers affected you overall during the last week:

None	0	1	2	3	4	5	6	7	8	9	10	Extreme

S6. Global assessment

Considering **all the ways your systemic sclerosis** has affected you during the last week, circle the number that best describes how you have been doing:

Very good	0	1	2	3	4	5	6	7	8	9	10	Very bad

Validation of ScleroID

COUNTRY_____ **Patient number /__/__/**

S7. We are interested in learning how your illness affects your ability to function in daily life. Please check (X) the one best answer which best describes your usual abilities OVER THE PAST WEEK:

	Without ANY Difficulty(0)	With SOME Difficulty(1)	With MUCH Difficulty(2)	UNABLE To Do(3)
DRESSING & GROOMING				
Are you able to:				
- Dress yourself, including tying shoelaces and doing buttons?	_____	_____	_____	_____
- Shampoo your hair?	_____	_____	_____	_____
ARISING				
Are you able to:				
- Stand up from a straight chair?	_____	_____	_____	_____
- Get in and out of bed?	_____	_____	_____	_____
EATING				
Are you able to:				
- Cut your meat?	_____	_____	_____	_____
- Lift a full cup or glass to your mouth?	_____	_____	_____	_____
- Open a new milk carton?	_____	_____	_____	_____
WALKING				
Are you able to:				
- Walk outdoors on flat ground?	_____	_____	_____	_____
- Climb up five steps?	_____	_____	_____	_____

Please check any AIDS OR DEVICES that you usually use for any of these activities:

_____ Cane
_____ Walker
_____ Crutches
_____ Wheelchair
_____ Devices used for dressing (button hook, zipper pull, long-handled shoe horn, etc.)
_____ Built up or special utensils
_____ Special or built up chair
_____ Other (Specify: _____)

Please check any categories for which you usually need HELP FROM ANOTHER PERSON:

_____ Dressing and Grooming
_____ Arising
_____ Eating
_____ Walking

Validation of ScleroID

COUNTRY_____ **Patient number /__/__/**

Please check the response which best describes your usual abilities OVER THE PAST WEEK:

	Without ANY Difficulty(0)	With SOME Difficulty(1)	With MUCH Difficulty(2)	UNABLE To Do(3)
HYGIENE				
Are you able to:				
- Wash and dry your body?	_____	_____	_____	_____
- Take a tub bath?	_____	_____	_____	_____
- Get on and off the toilet?	_____	_____	_____	_____
REACH				
Are you able to:				
- Reach and get down a 5 pound object (such as a bag of sugar) from just above your head?	_____	_____	_____	_____
- Bend down to pick up clothing from the floor?	_____	_____	_____	_____
GRIP				
Are you able to:				
- Open car doors?	_____	_____	_____	_____
- Open jars which have previously been opened?	_____	_____	_____	_____
- Turn faucets on and off?	_____	_____	_____	_____
ACTIVITIES				
Are you able to:				
- Run errands and shop?	_____	_____	_____	_____
- Get in and out of a car?	_____	_____	_____	_____
- Do chores such as vacuuming or yard work?	_____	_____	_____	_____

Please check any AIDS OR DEVICES that you usually use for any of these activities:

_____ Raised toilet seat
_____ Bathtub seat
_____ Jar opener (for jars previously opened)
_____ Other (Specify: _____)
_____ Bathtub bar
_____ Long-handled appliances for reach
_____ Long-handled appliances in bathroom

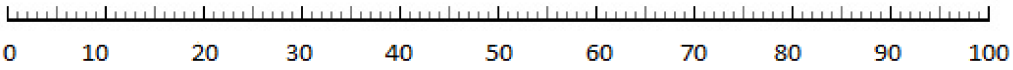
Please check any categories for which you usually need HELP FROM ANOTHER PERSON:

_____ Hygiene
_____ Reach
_____ Gripping and opening things
_____ Errands and chores

IN THE PAST WEEK, how much have your intestinal problems interfered with your daily activities?

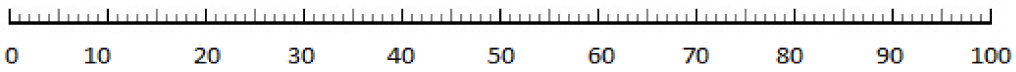
Validation of ScleroID

COUNTRY_____ **Patient number /__/__/**



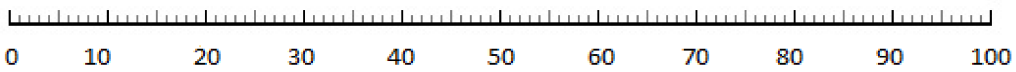
Does not interfere Very severe limitation

IN THE PAST WEEK, how much have your breathing problems interfered with your daily activities?



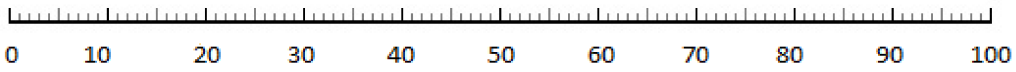
Do
es not interfere Very severe limitation

IN THE PAST WEEK, how much has Raynaud's interfered with your daily activities?



Does not interfere Very severe limitation

IN THE PAST WEEK, how much have your finger ulcers interfered with your daily activities?



Does not interfere Very severe limitation

S8. EQ-5D

By placing a tick in each group below, please indicate which statements best describe your own health state today.

Mobility

I have no problems in walking about ❒
I have some problems in walking about ❒
I am confined to bed ❒

Self-care

I have no problems with self-care ❒
I have some problems washing or dressing myself ❒
I am unable to wash or dress myself ❒

Usual activities (eg work, study, housework, family or leisure activities

Validation of ScleroID

COUNTRY_____ **Patient number /__/__/**

I have no problems with performing my usual activities ❒
I have some problems with performing my usual activities ❒
I am unable to perform my usual activities ❒

Pain / discomfort
I have no pain or discomfort ❒
I have moderate pain or discomfort ❒
I have extreme pain or discomfort ❒

Anxiety / depression
I am not anxious or depressed ❒
I am moderately anxious or depressed ❒
I am extremely anxious or depressed ❒

P10. Overall assessment of health status (SF-36)

1. In general, would you say your health is:	
Excellent	1
Very good	2
Good	3
Fair	4
Poor	5
2. **Compared to one year ago**, how would your rate your health in general **now**?	
Much better now than one year ago	1
Somewhat better now than one year ago	2
About the same	3
Somewhat worse now than one year ago	4
Much worse now than one year ago	5

The following items are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

(Circle One Number on Each Line)

	Yes, Limited a Lot	Yes, Limited a Little	No, Not limited at All

Validation of ScleroID

COUNTRY_____ **Patient number /__/__/**

3. **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	[1]	[2]	[3]
4. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	[1]	[2]	[3]
5. Lifting or carrying groceries	[1]	[2]	[3]
6. Climbing **several** flights of stairs	[1]	[2]	[3]
7. Climbing **one** flight of stairs	[1]	[2]	[3]
8. Bending, kneeling, or stooping	[1]	[2]	[3]
9. Walking **more than a mile**	[1]	[2]	[3]
10. Walking **several blocks**	[1]	[2]	[3]
11. Walking **one block**	[1]	[2]	[3]
12. Bathing or dressing yourself	[1]	[2]	[3]

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

(Circle One Number on Each Line)

	Yes	No
13. Cut down the amount of time you spent on work or other activities	1	2
14. **Accomplished less** than you would like	1	2
15. Were limited in the **kind** of work or other activities	1	2
16. Had **difficulty** performing the work or other activities (for example, it took extra effort)	1	2

During the **past 4 weeks,** have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems**(such as feeling depressed or anxious)? **(Circle One Number on Each Line)**

	Yes	No

Validation of ScleroID

COUNTRY_____ **Patient number /__/__/**

17. Cut down the **amount of time** you spent on work or other activities	1	2
18. **Accomplished less** than you would like	1	2
19. Didn't do work or other activities as **carefully** as usual	1	2

20. During the **past 4 weeks,** to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? **(Circle One Number)**

Not at all	1
Slightly	2
Moderately	3
Quite a bit	4
Extremely	5

21. How much **bodily** pain have you had during the **past 4 weeks**?

(Circle One Number)

None	1
Very mild	2
Mild	3
Moderate	4
Severe	5
Very severe	6

22. During the **past 4 weeks,** how much did **pain** interfere with your normal work (including both work outside the home and housework)? **(Circle One Number)**

Not at all	1
A little bit	2
Moderately	3

Validation of SclerolD

COUNTRY_____ **Patient number /__/__/**

Quite a bit 4

Extremely 5

These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling. **(Circle One Number on Each Line)**

How much of the time during the **past 4 weeks** . . .

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
23. Did you feel full of pep?	1	2	3	4	5	6
24. Have you been a very nervous person?	1	2	3	4	5	6
25. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
26. Have you felt calm and peaceful?	1	2	3	4	5	6
27. Did you have a lot of energy?	1	2	3	4	5	6
28. Have you felt downhearted and blue?	1	2	3	4	5	6
29. Did you feel worn out?	1	2	3	4	5	6
30. Have you been a happy person?	1	2	3	4	5	6
31. Did you feel tired?	1	2	3	4	5	6

32. During the **past 4 weeks,** how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)? **(Circle One Number)**

All of the time 1

Validation of ScleroID

COUNTRY_____ **Patient number /__/__/**

Most of the time	2
Some of the time	3
A little of the time	4
None of the time	5

How TRUE or FALSE is each of the following statements for you.

(Circle One Number on Each Line)

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
33. I seem to get sick a little easier than other people	1	2	3	4	5
34. I am as healthy as anybody I know	1	2	3	4	5
35. I expect my health to get worse	1	2	3	4	5
36. My health is excellent	1	2	3	4	5

Thank you for filling in this questionnaire

Validation of SclerolD

COUNTRY_____ **Patient number /__/__/**

RELIABILITY STUDY – PHYSICIAN CRF

(to be filled in 7+/-3 days after the baseline visit)

R1. Date of the visit */__/__/ /__/__/ 20__*
day month year

should be 7 days after the baseline visit (±3 days)

R2. **Do you confirm the main inclusion criteria?**

	Yes	No
R2.1. willingness to fill in the Reliability CRF after 7 +/- 3 days	❑	❑
R2.2. no major health change/medical intervention is forseeable/planed during the next 10 days.....	❑	❑

A negative answer to question 2.1 or 2.2 results in the non-inclusion of the patient in the reliability study.

Validation of ScleroID

COUNTRY_____ **Patient number /__/__/**

SENSITIVITY TO CHANGE STUDY – PATIENT CRF

Today's Date: Day /__/__/ Month /__/__/ Year 20/__/__/

Please cross the correct answer:

S1. Since you last filled in this questionnaire, do you consider your systemic sclerosis to be stable? ..... yes ❑ no ❑

S2. Since you last filled in this questionnaire, has your treatment for your systemic sclerosis been changed? ..... yes ❑ no ❑

S3. **Think about all the ways in which the systemic sclerosis has affected you during the last week, how would you consider this state?** (Mark "**X**" in only one box below)

❑ Very good
❑ Good
❑ Acceptable
❑ Bad
❑ Very bad

S4. Think about all the ways your systemic sclerosis has affected you during the last week. **Compared to 6 months ago, how has the overall state of your disease been during the last week?** (Mark "**X**" in only one box below)

☐ Much improved
☐ Moderately improved
☐ Stable (mostly unchanged)
☐ Moderately worsened
☐ Much worsened

Validation of ScleroID

COUNTRY_____ **Patient number /__/__/**

S5. The EULAR Scleroderma Impact of Disease Score (ScleroID)

How much have the different aspects of systemic sclerosis affected you during the last week? Please mark your responses on the scale by choosing the appropriate number for each of the following dimensions:

Raynaud's phenomenon:

Circle the number that best describes the severity of your Raynaud's phenomenon during the last week:

None	0	1	2	3	4	5	6	7	8	9	10	Extreme

Hand function:

Circle the number that best describes your hand function limitations due to your systemic sclerosis during the last week:

No limitation	0	1	2	3	4	5	6	7	8	9	10	Extreme limitation

Upper gastrointestinal tract symptoms (e.g. swallowing difficulties, reflux, vomiting):

Circle the number that best describes the severity of your upper gastrointestinal tract symptoms due to your systemic sclerosis during the last week:

None	0	1	2	3	4	5	6	7	8	9	10	Extreme

Pain:

Circle the number that best describes the pain you felt due to your systemic sclerosis during the last week:

None	0	1	2	3	4	5	6	7	8	9	10	Extreme

Fatigue:

Circle the number that best describes the impact of overall fatigue due to your systemic sclerosis during the last week:

None	0	1	2	3	4	5	6	7	8	9	10	Extreme

Lower gastrointestinal tract symptoms (e.g. bloating, diarrhea, constipation, anal incontinence):

Circle the number that best describes the severity of lower gastrointestinal tract symptoms during the last week:

None	0	1	2	3	4	5	6	7	8	9	10	Extreme

Limitations of life choices and activities (e.g. social life, personal care, work):

Circle the number that best describes how severe the limitations of life choices and activities due to your systemic sclerosis were during the last week:

No	0	1	2	3	4	5	6	7	8	9	10	Extreme

Validation of ScleroID

COUNTRY_____ **Patient number /__/__/**

Body mobility:

Circle the number that best describes how much your body mobility was affected due to your systemic sclerosis during the last week:

Not affected	0	1	2	3	4	5	6	7	8	9	10	Extremely affected

Breathlessness:

Circle the number that best describes how severe your breathlessness due to systemic sclerosis was during the last week:

None	0	1	2	3	4	5	6	7	8	9	10	Extreme

Digital ulcers:

Circle the number that best describes how much your digital ulcers affected you overall during the last week:

None	0	1	2	3	4	5	6	7	8	9	10	Extreme

S6. Global assessment

Considering **all the ways your systemic sclerosis** has affected you during the last week, circle the number that best describes how you have been doing:

Very good	0	1	2	3	4	5	6	7	8	9	10	Very bad

Validation of ScleroID

COUNTRY_____ **Patient number /__/__/**

S7. We are interested in learning how your illness affects your ability to function in daily life. Please check (X) the one best answer which best describes your usual abilities OVER THE PAST WEEK:

	Without ANY Difficulty(0)	With SOME Difficulty(1)	With MUCH Difficulty(2)	UNABLE To Do(3)
DRESSING & GROOMING				
Are you able to:				
- Dress yourself, including tying shoelaces and doing buttons?	_____	_____	_____	_____
- Shampoo your hair?	_____	_____	_____	_____
ARISING				
Are you able to:				
- Stand up from a straight chair?	_____	_____	_____	_____
- Get in and out of bed?	_____	_____	_____	_____
EATING				
Are you able to:				
- Cut your meat?	_____	_____	_____	_____
- Lift a full cup or glass to your mouth?	_____	_____	_____	_____
- Open a new milk carton?	_____	_____	_____	_____
WALKING				
Are you able to:				
- Walk outdoors on flat ground?	_____	_____	_____	_____
- Climb up five steps?	_____	_____	_____	_____

Please check any AIDS OR DEVICES that you usually use for any of these activities:

_____ Cane
_____ Walker
_____ Crutches
_____ Wheelchair
_____ Devices used for dressing (button hook, zipper pull, long-handled shoe horn, etc.)
_____ Built up or special utensils
_____ Special or built up chair
_____ Other (Specify: _____)

Please check any categories for which you usually need HELP FROM ANOTHER PERSON:

_____ Dressing and Grooming
_____ Arising
_____ Eating
_____ Walking

Validation of ScleroID

COUNTRY_____ **Patient number /__/__/**

Please check the response which best describes your usual abilities OVER THE PAST WEEK:

	Without ANY Difficulty(0)	With SOME Difficulty(1)	With MUCH Difficulty(2)	UNABLE To Do(3)
HYGIENE				
Are you able to:				
- Wash and dry your body?	_____	_____	_____	_____
- Take a tub bath?	_____	_____	_____	_____
- Get on and off the toilet?	_____	_____	_____	_____
REACH				
Are you able to:				
- Reach and get down a 5 pound object (such as a bag of sugar) from just above your head?	_____	_____	_____	_____
- Bend down to pick up clothing from the floor?	_____	_____	_____	_____
GRIP				
Are you able to:				
- Open car doors?	_____	_____	_____	_____
- Open jars which have previously been opened?	_____	_____	_____	_____
- Turn faucets on and off?	_____	_____	_____	_____
ACTIVITIES				
Are you able to:				
- Run errands and shop?	_____	_____	_____	_____
- Get in and out of a car?	_____	_____	_____	_____
- Do chores such as vacuuming or yard work?	_____	_____	_____	_____

Please check any AIDS OR DEVICES that you usually use for any of these activities:

_____ Raised toilet seat
_____ Bathtub seat
_____ Jar opener (for jars previously opened)
_____ Other (Specify: _____)
_____ Bathtub bar
_____ Long-handled appliances for reach
_____ Long-handled appliances in bathroom

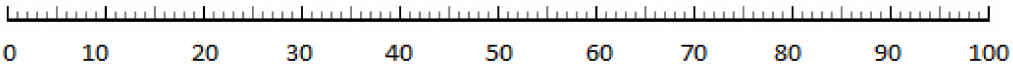
Please check any categories for which you usually need HELP FROM ANOTHER PERSON:

_____ Hygiene
_____ Reach
_____ Gripping and opening things
_____ Errands and chores

IN THE PAST WEEK, how much have your intestinal problems interfered with your daily activities?

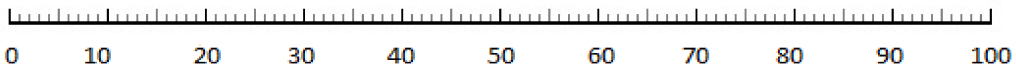
Validation of ScleroID

COUNTRY_____ **Patient number /__/__/**



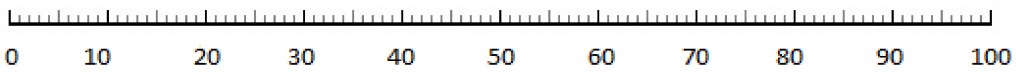
Does not interfere Very severe limitation

IN THE PAST WEEK, how much have your breathing problems interfered with your daily activities?



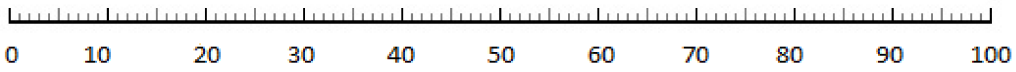
Do
es not interfere Very severe limitation

IN THE PAST WEEK, how much has Raynaud's interfered with your daily activities?



Does not interfere Very severe limitation

IN THE PAST WEEK, how much have your finger ulcers interfered with your daily activities?



Does not interfere Very severe limitation

S8. EQ-5D

By placing a tick in each group below, please indicate which statements best describe your own health state today.

Mobility

I have no problems in walking about ❒
I have some problems in walking about ❒
I am confined to bed ❒

Self-care

I have no problems with self-care ❒
I have some problems washing or dressing myself ❒
I am unable to wash or dress myself ❒

Usual activities (eg work, study, housework, family or leisure activities

Validation of ScleroID

COUNTRY_____ **Patient number /__/__/**

I have no problems with performing my usual activities ❒
I have some problems with performing my usual activities ❒
I am unable to perform my usual activities ❒

Pain / discomfort
I have no pain or discomfort ❒
I have moderate pain or discomfort ❒
I have extreme pain or discomfort ❒

Anxiety / depression
I am not anxious or depressed ❒
I am moderately anxious or depressed ❒
I am extremely anxious or depressed ❒

P10. Overall assessment of health status (SF-36)

1. In general, would you say your health is:	
Excellent	1
Very good	2
Good	3
Fair	4
Poor	5
2. **Compared to one year ago**, how would your rate your health in general **now**?	
Much better now than one year ago	1
Somewhat better now than one year ago	2
About the same	3
Somewhat worse now than one year ago	4
Much worse now than one year ago	5

The following items are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

(Circle One Number on Each Line)

	Yes, Limited a Lot	Yes, Limited a Little	No, Not limited at All

Validation of ScleroID

COUNTRY_____ **Patient number /__/__/**

3. **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	[1]	[2]	[3]
4. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	[1]	[2]	[3]
5. Lifting or carrying groceries	[1]	[2]	[3]
6. Climbing **several** flights of stairs	[1]	[2]	[3]
7. Climbing **one** flight of stairs	[1]	[2]	[3]
8. Bending, kneeling, or stooping	[1]	[2]	[3]
9. Walking **more than a mile**	[1]	[2]	[3]
10. Walking **several blocks**	[1]	[2]	[3]
11. Walking **one block**	[1]	[2]	[3]
12. Bathing or dressing yourself	[1]	[2]	[3]

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

(Circle One Number on Each Line)

	Yes	No
13. Cut down the amount of time you spent on work or other activities	1	2
14. **Accomplished less** than you would like	1	2
15. Were limited in the **kind** of work or other activities	1	2
16. Had **difficulty** performing the work or other activities (for example, it took extra effort)	1	2

During the **past 4 weeks,** have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems**(such as feeling depressed or anxious)? **(Circle One Number on Each Line)**

	Yes	No

Validation of ScleroID

COUNTRY_____ **Patient number /__/__/**

17. Cut down the **amount of time** you spent on work or other activities	1	2
18. **Accomplished less** than you would like	1	2
19. Didn't do work or other activities as **carefully** as usual	1	2

20. During the **past 4 weeks,** to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? **(Circle One Number)**

Not at all	1
Slightly	2
Moderately	3
Quite a bit	4
Extremely	5

21. How much **bodily** pain have you had during the **past 4 weeks**?

(Circle One Number)

None	1
Very mild	2
Mild	3
Moderate	4
Severe	5
Very severe	6

22. During the **past 4 weeks,** how much did **pain** interfere with your normal work (including both work outside the home and housework)? **(Circle One Number)**

Not at all	1
A little bit	2
Moderately	3

Validation of SclerolD

COUNTRY_____ **Patient number /__/__/**

Quite a bit 4

Extremely 5

These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling. **(Circle One Number on Each Line)**

How much of the time during the **past 4 weeks** . . .

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
23. Did you feel full of pep?	1	2	3	4	5	6
24. Have you been a very nervous person?	1	2	3	4	5	6
25. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
26. Have you felt calm and peaceful?	1	2	3	4	5	6
27. Did you have a lot of energy?	1	2	3	4	5	6
28. Have you felt downhearted and blue?	1	2	3	4	5	6
29. Did you feel worn out?	1	2	3	4	5	6
30. Have you been a happy person?	1	2	3	4	5	6
31. Did you feel tired?	1	2	3	4	5	6

32. During the **past 4 weeks,** how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)? **(Circle One Number)**

All of the time 1

Validation of ScleroID

COUNTRY_____ **Patient number /__/__/**

Most of the time	2
Some of the time	3
A little of the time	4
None of the time	5

How TRUE or FALSE is each of the following statements for you.

(Circle One Number on Each Line)

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
33. I seem to get sick a little easier than other people	1	2	3	4	5
34. I am as healthy as anybody I know	1	2	3	4	5
35. I expect my health to get worse	1	2	3	4	5
36. My health is excellent	1	2	3	4	5

Thank you for filling in this questionnaire

Validation of ScleroID

COUNTRY_____ **Patient number /__/__/**

SENSITIVITY TO CHANGE STUDY- PHYSICIAN CRF

(to be filled at visits occurring 6, respectively 12 months after the baseline visit)

S1. Date of the visit */__/__/ /__/__/ 20__*
day month year

S2. Do you confirm the main inclusion criteria?

	Yes	No
S2.1. Patient had active disease AT BASELINE as defined by the physician	❑	❑
S2.2. A follow-up visit at 6 and 12 months or at least at 12 months after baseline is feasible	❑	❑

A negative answer results in the non-inclusion of the patient in the sensitivity to change study.

S3. SSc characteristics

Please make sure that all necessary items of the corresponding EUSTAR dataset are evaluated and filled into the system (clinical features, laboratory values etc.) AND the patient fills in the necessary questionnaires/CRF.

S4. Physician's global assessment of SSc

Considering all the ways systemic sclerosis has affected your patient during the last week, circle the number that best describes how he/she has been doing:

Very good	0	1	2	3	4	5	6	7	8	9	10	Very bad