

# Protocol for Evaluation and Comparison of Tolerability and Acceptability of Different Alcohol-based Handrubs: Method 2

## Summary

### Study Method

- Approximately 40 volunteer participants using at least 30 ml of product per day
- **Randomised study:** participants are allocated at random (by chance only) to the test products
- **Double-blind study:** neither the participant nor the observer (including data manager) is aware of product content or allocation
- **Cross over study:** each participant tests all formulations in a sequential way

### Information and Instructions

- The study usually concerns two hand hygiene products: formulas A and B, but it can be used to compare several products
- The health-care workers must meet the observer on the first day and collect the bottle; on the last day they must meet again
- The observer distributes bottles without any label to identify the contained solution (both the observer and the health-care worker are blinded) but has a number that has been allocated by the pharmacy and identifies the formulation. Each bottle must have a different number
- For at least 3-5 consecutive days (minimal test period), only the test product must be used for hand antisepsis
- An evaluation of skin integrity by the observer is required before and after the use of each test product
- The participant must complete a questionnaire after using each test product
- Each test period must be separated by a washout period\* corresponding to at least 2 days off work
- The amount of test product distributed is recorded and compared with the final amount left over
- Opened bottles, either empty or partially full, must be returned for weighing to the observer at the end of each test period
- The participant is requested not to use hand lotion or cream during the test periods
- The participant must inform the observer if he/she stops the test prematurely

**\*Wash-out period:** gap between two test periods, during which no alcohol-based handrub is used, and which makes it possible to mitigate the effects of use and to eliminate the previous product.

## Detailed Instructions

This method is more complex than Method 1 ("Protocol for Evaluation of Tolerability and Acceptability of Alcohol-based Handrub in Use or Planned to be Introduced"), and is intended to be used **only** with the purpose **to compare** skin tolerability and acceptability of several products. This means that the choice of product may depend on the test results and the product's compliance with predetermined criteria for tolerability and acceptability.

### Proposed criteria, according to the assigned ranking

#### Criteria for product acceptability:

- Questionnaire – Part 2 "Product evaluation" – Items Colour & Fragrance:  $\geq 50\%$  above 4
- Questionnaire – Part 2 "Product evaluation" – Other items:  $\geq 75\%$  above 4

#### Criteria for skin tolerability:

- Questionnaire – Part 2 "Self evaluation of state of skin on hands" – all items:  $\geq 75\%$  above 4
- Questionnaire – Part 2 "Evaluation of the state of skin on hands by the observer":  $\geq 75\%$  below 2

- Several products are compared over given periods separated by breaks in work (weekly rest days, holidays, training, etc)
- Each test period lasts for at least 3-5 consecutive days
- The wash-out period\* between the testing of two products is at least 2 rest days

**\*Wash-out period:** gap between two test periods, during which no alcohol-based handrub is used, and which makes it possible to mitigate the effects of use and to eliminate the previous product.

Skin condition is evaluated by the observer before and after each product is tested (objective evaluation). Participants also evaluate the state of their skin after the tests and give their views on the products (subjective evaluation).

- The products undergo **double blind testing**. This means that no one who is involved in evaluating the effects of the products tested (participant, observer, analyst) knows the composition of the products being tested;
- The study is randomized\*\*. This means that participants are volunteers who are assigned a number; the number determines the order in which the products are distributed. Numbers are assigned to participants as they are enrolled. Neither the participants nor the observers are able to deliberately decide how the products are distributed

### \*\*Randomization = random distribution

The randomization and control form is an essential tool to help observers organize their work, which has to be adapted to that of the participants. In that observers should organize themselves around the participants' variable working hours. Appointments between participants and observers should not interfere with the participants' work. For this reason, they are scheduled either before or after work depending on whether they concern the start or end of a test period, and take place at the workplace. It is possible to make appointments with several participants at the same time, although each appointment must concern a different stage in the study. In this case, it is necessary to use a control tool capable of closely monitoring the randomized test, and which is kept up to date.

We propose a form whose predetermined structure determines the random distribution (two lines per participant), corresponding to the testing of two products. If necessary, add the number of lines corresponding to the number of products tested and whose columns correspond to the identity of the participants, the products, the scheduling of the test periods and appointments and verification that each stage of the study has been completed.

- Participants carry out cross-testing of the products; this means that each participant tests each product.

**The test consists of the following stages:**

1. Preparation of the product to be tested
2. Information, identification of participants, and individual test planning
3. Use of the product and evaluation
4. Data entry and analysis
5. Presentation of the results

**1. Preparation of the products****The pharmacist is responsible for:**

- Preparing the products. Neither the participant, the observer nor the analyst must know their composition or in which bottle they are placed (double blind test)
- (Re)-packaging each of the products in plain, (non-recognizable) identical pocket-sized bottles (75–125 ml)
- Marking each bottle with a pharmacy number, whose correspondence to a product is kept confidential
- Recording the amount of product in each bottle against the pharmacist's number
- Informing the observer of the volume to weight ratio (1 ml = x g)
- Placing the bottles in crates, which correspond to groups, on the basis of their correspondence with the products (the same number of groups as products tested) and ensuring their timely distribution to the health-care units in which the participants work

**2. Information, identification, planning****The observer's tasks are to:**

- Obtain the support of the service's supervisors for testing the product among their staff
- Organize information sessions for potential recruits for the test among health-care workers (aim, procedure, conditions, constraints, etc)
- Identify by name approximately 40 volunteer health-care workers and give them an identification number determined by the order in which they are recruited (participant number) using the randomization and control form

It is essential to know each participants' identity in order for the observer to organize and carry out the study; their identity is concealed, however when the data are analyzed. The number assigned to participants is copied onto the questionnaires, as well as the evaluation and planning forms and the bottles distributed on the first days of the test.

**Practical advice:** as observers generally conduct the study alone, they are unable to be in several places at the once. Wherever possible, recruit participants who work in the same service. If this is not possible, and depending on the number of participants in each service / unit, it is preferable to conduct the study successively in each service concerned; the products must be available at the participants' workplace and distributed on the spot.

- Obtain a temporary workplace in the health-care service/unit for the duration of the study, in which to interview participants and store products
- Schedule appointments with each participant on the basis of their working hours, to give the schedule in writing to each participant and to copy it onto the randomization and control form

Appointments take place in the health-care service/unit in which the participants work and in accordance with the following conditions:

- Each product is tested for at least 3 working days;
- Each test period is separated from the next by at least 2 **rest days**, during which no alcohol-based product is used

#### **Appointments for the first product tested:**

- On Day 1, before the participants start work, the observer should distribute the bottles of the product being tested and Parts 1 and 2 of the questionnaire, and evaluate the state of the participants' hands
- After at least 3-5 consecutive days of work, after the participants have finished work, they should return the completed Parts 1 and 2 of the questionnaires and the bottles distributed, and the observer should evaluate the state of the participants' hands.

Then, after at least 2 rest days:

#### **Appointments for the second product tested:**

- On Day 1, before the participants start work, the observer should distribute the bottles of the product being tested and Parts 1 and 2 of the questionnaire, and evaluate the state of the participants' hands
- After at least 3 consecutive days of work, after the participants have finished work, they should return the completed Parts 1 and 2 of the questionnaires and the bottles distributed, and the observer should evaluate the state of the participants' hands.

Repeat, as many times as there are products to be tested.

**Note:** if any participant has to withdraw from the test for an unforeseen reason other than unbearable deterioration of the skin on their hands, a further test period is scheduled.

- Count the number of bottles distributed and to record the number distributed, their pharmacy number and the group to which they are assigned on the randomization form and Part 2 of the questionnaire

The number of bottles distributed depends on the size of the bottles and the number of days taken up by the test. As an example, for a daily consumption of 30–50 ml, two 100 ml bottles are more than enough for 3 working days and three 100 ml bottles for 5 days.

- Ensure supplies of the alcohol-based handrub are available to participants for the duration of the test
- Record each stage of the study for each participant on the randomization form
- Measure the amount of each product used

Two operations are required to calculate the amount of product used (on the basis of the weight of a given volume of product): 1 ml = x g (reference weight)

1. Convert the remaining weight (g) into remaining volume (ml): remaining weight/reference weight  
(x g) = ml remaining
2. Subtract the amount remaining from the amount distributed = amount used

- Evaluate the state of the skin on the participants' hands before and after the test, using the scores proposed

### 3. Use and evaluation of the product

#### Each participant undertakes to:

- Only use the alcohol-based handrub being tested (except in situations in which the indication to wash with soap and water applies) for hand hygiene during the respective test period (see Planning for Evaluation of Tolerability and Acceptability of Different Alcohol-based Handrubs: Method 2)
- Use no hand-care cream or lotion during the test period
- Fill in the questionnaire – Part 2 (5 minutes per product tested) after each test period
- Fill in the questionnaire – Part 1 (1 x 5 minutes) after the first test period
- Meet with the observer before and after each test period for an evaluation of the state of the skin on their hands (objective skin evaluation – Part 2), distribution and return of the bottles and questionnaires (3 minutes per appointment)
- Return all the bottles of product distributed for each test period, regardless of how much they have used
- Not change their working hours once the test periods have been scheduled, and if they have to do so, to inform the observer

Participants evaluate the product using the questionnaire – Part 2; the state of skin evaluation is made up of a subjective evaluation by participants using Part 2 of the questionnaire<sup>1</sup> and an objective evaluation by the observer using validated scales and scores<sup>2</sup> (objective skin evaluation – Part 2). The data are analysed on the basis of risk factors of skin damage, regardless of the composition of the products (questionnaire – Part 1).

### 4. Data entry and analysis

- Before entering any data for analysis, the observer should complete and classify the different documents and check their content and consistency

#### Each participant should be assigned:

- 1 numbered line on the randomization form
  - 1 questionnaire – Part 1
  - x questionnaires – Part 2 (depending on the number of products to be tested) including the skin evaluation form
- Once the documents have been classified and checked, the observer must remove any name and keep only the participants' identification number
  - The data are entered directly into the Data Entry Analysis Tool available from WHO or sent to the local data manager
  - The data are analysed, and when the results are known, the pharmacist lifts the confidentiality covering the composition of the product tested and the criteria for tolerability and acceptability

### 5. Presentation of the results

When the results of the data analysis are available, the pharmacist, the observer and any other key professional involved in the testing agree on how to present them to the administrative and managerial staff and to the participants, and on how to disseminate them, if they are likely to have a direct impact on all the staff.

<sup>1</sup> Pittet D, Allegranzi B, Sax H, Chraïti M-N, Griffiths W, Richet H. Double-blind, randomized, crossover trial of 3 hand rub formulations: fast-track evaluation of tolerability and acceptability. *Infection Control and Hospital Epidemiology* 2007;28:1344-51.

<sup>2</sup> Larson EL, Aiello AE, Bastyr J, et al. Assessment of two hand hygiene regimens for intensive care unit personnel. *Critical Care Medicine* 2001; 29: 944-951.



### Questionnaire – Part 1

(To complete **once** per participant)

Participant no:

Date of questionnaire's return: (day / month / year)

#### Evaluation of factors influencing skin tolerance

Age:

Sex:  F  M

Professional group:

- Nurse     Midwife     Student     Auxiliary     Medical doctor     Medical student  
 Therapist     Technician     Other

Skin:

- Very fair with freckles     Fair ± freckles     Light brown     Brown  
 Dark brown     Black

Climate:

- Polar     Continental / Temperate     Subtropical / Mediterranean     Tropical / Equatorial  
 Desert

Present season:

- Dry     Humid     Cold     Hot     Intermediate

Do you have non work-related activity(ies) likely to cause damage to your skin?  Yes  No

Do you normally use a protective hand lotion/cream (outside the test period)?

- As often as possible     Several times/day     Once/day  
 Sometimes, depending on the season     Rarely     Never

Do you develop irritative dermatitis?

- Never     Sometimes (depending on season/activity)     Always

Do you develop atopic dermatitis?

- Yes     No

Do you develop rhinitis / allergic conjunctivitis?

- Yes     No



Are you asthmatic?

Yes  No

Do you have a known intolerance to alcohol?

Yes  No

Evaluation of frequency of hand hygiene practices

Do you work full-time?

Yes  No

If part-time, please indicate which of the following best fits your work

< 50%  50%  60%  70%  80%  90%

For how long have you been using an alcohol-based hand hygiene product at work?

It's the first time  Since < 1 year  Since > 1 year and < 5 years  Since > 5 years

Do you think you can improve your own hand hygiene compliance?

Yes  No  Perhaps

It may be difficult for you to use an alcohol-based hand hygiene product because of:

**Forgetfulness** Always        Never

**Lack of time** Always        Never

**Damaged skin** Always        Never



## Questionnaire – Part 2

(To be completed for each test product)

<b>Participant n°:</b>	<input type="text"/>	<b>Product:</b>	<input type="text"/>
<b>Date of questionnaire's return (day / month / year):</b>	<input type="text"/>	<b>Participant name:</b>	<input type="text"/>
<b>Bottle n°:</b>	<input type="text"/>	<b>Amount of Product used (ml):</b>	<input type="text"/>

### Evaluation of frequency of hand hygiene practices

**During how many consecutive working days have you used the test product?**

- 3 days     4 days     5 days     6 days     7 days     > 7 days

**How often do you have direct contact with patients during your working day (during the test period)?**

- < 1 contact     Between 1 and 5     Between 6 and 10     Between 11 and 15     > 15 contacts

**In what percentage of times where hand hygiene is recommended, do you really clean your hands?**

- 0%     10%     20%     30%     40%     50%     60%     70%     80%     90%     100%

**Has the present study changed your hand hygiene practice?**

- Yes     No

**During your last 5 opportunities for hand hygiene, how many times did you use handrubbing to clean your hands?**

- 0     1     2     3     4     5

**On average, how often do you practise hand hygiene during a working hour (during the test period)?**

- < 1     Between 1 and 5     Between 6 and 10     Between 11 and 15     > 15



**Evaluation of the test product**

**What is your opinion of the test product for hand hygiene?**

<b>Colour</b>	Unpleasant	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Pleasant
<b>Smell</b>	Unpleasant	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Pleasant
<b>Texture</b>	Very sticky	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Not sticky at all
<b>Irritation (stinging)</b>	Very irritating	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Not irritating
<b>Drying effect</b>	Very much	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Not at all
<b>Ease of use</b>	Very difficult	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Very easy
<b>Speed of drying</b>	Very slow	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Very fast
<b>Application</b>	Very unpleasant	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Very pleasant
<b>Overall evaluation</b>	Dissatisfied	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Very satisfied

**Are there differences between the test product and the product used in your hospital?**

Major         No

**Which product do you prefer?**

Usual product  Test product  No preference

**Do you think that the test product could improve your hand hygiene compliance?**

Yes, absolutely         Not at all

**Evaluation of skin condition**

**Self-assessment of the skin on your hands (after use of the test product):**

<b>Appearance</b> (supple, red, blotchy, rash)	Abnormal	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Normal
<b>Intactness</b> (abrasions, fissures)	Abnormal	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Normal
<b>Moisture content</b> (dryness)	Abnormal	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Normal
<b>Sensation</b> (itching, burning, soreness)	Abnormal	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Normal

**How would you assess the overall integrity of the skin on your hands?**

Very altered         Perfect

**Thank you for your participation!**

**Scales to evaluate skin condition by the observer (objective evaluation)**

	Before					After				
<b>Redness</b>	0	1	2	3	4	0	1	2	3	4
<i>0=no redness, 1=slight redness or blotchiness, 2=moderate redness, uniformly distributed, 3=bright red, widespread, 4=very bright red with oedema present</i>										
<b>Scaliness</b>	0	1	2	3		0	1	2	3	
<i>0=non scaliness, 1=very slight and occasional, 2=moderate, 3=very pronounced separation of scale edges from skin</i>										
<b>Fissures</b>	0	1	2	3		0	1	2	3	
<i>0=no fissure 1=very fine, 2=large, either single or multiple, 3=extensive cracks with bleeding or seeping</i>										
<b>Visual Scoring of Skin Scale</b>										
No observable scale or irritation of any kind	0					0				
Occasional scale that is not necessarily uniformly distributed	1					1				
Dry skin and/or redness	2					2				
Very dry skin with whitish appearance, rough to touch and/or redness, but without fissures	3					3				
Cracked skin surface but without bleeding/seeping	4					4				
Extensive cracking of skin surface with bleeding/seeping	5					5				

## Planning for Evaluation of Tolerability and Acceptability of Different Alcohol-based Handrubs – Method 2

**Name:**

**Participant n°:**

**Test Period: (day / month / year)** From / / to / /

**Please note the timetable of your appointments**

WHEN			WHY
<b>1st product</b>	<b>Date and time (before)</b>	/ / (day / month / year) Time: <input type="text"/>	<b>To collect bottles containing the test product</b> (amount defined according to number of working days and volume of bottles) <b>To collect the questionnaire – Parts 1 &amp; 2</b> <b>For skin assessment by the observer</b>
	<b>Date and time (after)</b>	/ / (day / month / year) Time: <input type="text"/>	<b>To return all bottles</b> <b>To return the questionnaire – Parts 1 &amp; 2</b> <b>For skin assessment by the observer</b>
<b>2nd product</b>	<b>Date and time (before)</b>	/ / (day / month / year) Time: <input type="text"/>	<b>To collect bottles containing the test product</b> (amount defined according to number of working days and volume of bottles) <b>To collect the questionnaire – Part 2</b> <b>For skin assessment by the observer</b>
	<b>Date and time (after)</b>	/ / (day / month / year) Time: <input type="text"/>	<b>To return all bottles</b> <b>To return the questionnaire – Part 2</b> <b>For skin assessment by the observer</b>

... to repeat according to the number of test products

The observer can be contacted during working hours throughout the test period for questions and/or problems on the following number:

**Telephone Number:**

## Check and Randomisation Form: Method 2

(designed for a two product-test)

Participant N°	Name	Formulation	Appointment	Distributed bottles/ Returned bottles	Remaining weight/ Amount used	Questionnaire check	Skin assessment	
1		Group A	Start day <input type="text"/> / <input type="text"/> / <input type="text"/> Start Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Distributed <input type="checkbox"/>	Before <input type="checkbox"/>	
			End day <input type="text"/> / <input type="text"/> / <input type="text"/> End Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Returned <input type="checkbox"/>	After <input type="checkbox"/>	
				N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Part 1 <input type="checkbox"/>		
		Final Check OK <input type="checkbox"/>	Group B	Start day <input type="text"/> / <input type="text"/> / <input type="text"/> Start Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Distributed <input type="checkbox"/>	Before <input type="checkbox"/>
				End day <input type="text"/> / <input type="text"/> / <input type="text"/> End Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Returned <input type="checkbox"/>	After <input type="checkbox"/>
					N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml		
2		Group B	Start day <input type="text"/> / <input type="text"/> / <input type="text"/> Start Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Distributed <input type="checkbox"/>	Before <input type="checkbox"/>	
			End day <input type="text"/> / <input type="text"/> / <input type="text"/> End Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Returned <input type="checkbox"/>	After <input type="checkbox"/>	
				N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Part 1 <input type="checkbox"/>		
		Final Check OK <input type="checkbox"/>	Group A	Start day <input type="text"/> / <input type="text"/> / <input type="text"/> Start Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Distributed <input type="checkbox"/>	Before <input type="checkbox"/>
				End day <input type="text"/> / <input type="text"/> / <input type="text"/> End Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Returned <input type="checkbox"/>	After <input type="checkbox"/>
					N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml		

Participant N°	Name	Formulation	Appointment	Distributed bottles/ Returned bottles	Remaining weight/ Amount used	Questionnaire check	Skin assessment
3		Group A	Start day <input type="text"/> / <input type="text"/> / <input type="text"/> Start Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Distributed <input type="checkbox"/>	Before <input type="checkbox"/>
			End day <input type="text"/> / <input type="text"/> / <input type="text"/> End Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Returned <input type="checkbox"/>	After <input type="checkbox"/>
				N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Part 1 <input type="checkbox"/>	
	Final Check OK <input type="checkbox"/>	Group B	Start day <input type="text"/> / <input type="text"/> / <input type="text"/> Start Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Distributed <input type="checkbox"/>	Before <input type="checkbox"/>
			End day <input type="text"/> / <input type="text"/> / <input type="text"/> End Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Returned <input type="checkbox"/>	After <input type="checkbox"/>
				N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml		
4		Group B	Start day <input type="text"/> / <input type="text"/> / <input type="text"/> Start Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Distributed <input type="checkbox"/>	Before <input type="checkbox"/>
			End day <input type="text"/> / <input type="text"/> / <input type="text"/> End Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Returned <input type="checkbox"/>	After <input type="checkbox"/>
				N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Part 1 <input type="checkbox"/>	
	Final Check OK <input type="checkbox"/>	Group A	Start day <input type="text"/> / <input type="text"/> / <input type="text"/> Start Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Distributed <input type="checkbox"/>	Before <input type="checkbox"/>
			End day <input type="text"/> / <input type="text"/> / <input type="text"/> End Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Returned <input type="checkbox"/>	After <input type="checkbox"/>
				N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml		

Participant N°	Name	Formulation	Appointment	Distributed bottles/ Returned bottles	Remaining weight/ Amount used	Questionnaire check	Skin assessment
5		Group A	Start day <input type="text"/> / <input type="text"/> / <input type="text"/> Start Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Distributed <input type="checkbox"/>	Before <input type="checkbox"/>
			End day <input type="text"/> / <input type="text"/> / <input type="text"/> End Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Returned <input type="checkbox"/>	After <input type="checkbox"/>
				N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Part 1 <input type="checkbox"/>	
	Final Check OK <input type="checkbox"/>	Group B	Start day <input type="text"/> / <input type="text"/> / <input type="text"/> Start Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Distributed <input type="checkbox"/>	Before <input type="checkbox"/>
			End day <input type="text"/> / <input type="text"/> / <input type="text"/> End Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Returned <input type="checkbox"/>	After <input type="checkbox"/>
				N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml		
6		Group B	Start day <input type="text"/> / <input type="text"/> / <input type="text"/> Start Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Distributed <input type="checkbox"/>	Before <input type="checkbox"/>
			End day <input type="text"/> / <input type="text"/> / <input type="text"/> End Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Returned <input type="checkbox"/>	After <input type="checkbox"/>
				N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Part 1 <input type="checkbox"/>	
	Final Check OK <input type="checkbox"/>	Group A	Start day <input type="text"/> / <input type="text"/> / <input type="text"/> Start Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Distributed <input type="checkbox"/>	Before <input type="checkbox"/>
			End day <input type="text"/> / <input type="text"/> / <input type="text"/> End Time <input type="text"/>	N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml	Returned <input type="checkbox"/>	After <input type="checkbox"/>
				N° <input type="text"/> <input type="checkbox"/>	<input type="text"/> g <input type="text"/> ml		

Lines must be added according to the number of participants