# TREAT eDelphi consensus meeting

25th October 2016

Amsterdam, The Netherlands

# Minutes

## List of attendees

| Participant name | Stakeholder group | Country |
|---|---|---|
| Amanda Roberts | Patient | UK |
| Amit Bodhani | Industry representative | USA |
| Anna Belloni Fortina | Health care professional: doctor | Italy |
| Anne Speirs | Health care professional: nurse | UK |
| Anthea Wilson | Patient | UK |
| Caoimhe Fahy | Health care professional: doctor | Ireland |
| Carle Paul | Health care professional: doctor | France |
| Carsten Flohr | Health care professional: doctor | UK |
| Christian Apfelbacher | Non-clinical researcher | Germany |
| Christian Vestergaard | Health care professional: doctor | Denmark |
| Efstratios Vakirlis | Health care professional: doctor | Greece |
| Elke Weisshaar | Health care professional: doctor | Germany |
| Erik-Jan Dammers | Industry representative | The Netherlands |
| Fanneke Alkemade | Industry representative | The Netherlands |
| Gabrielle Appel | Patient buddy and health care professional: nurse | The Netherlands |
| Gitta Giskes | Health care professional: nurse | The Netherlands |
| Hilary Selles-Basford | Patient | The Netherlands |
| Jan Slachmuylders | Industry representative | The Netherlands |
| Jane Ravenscroft | Health care professional: doctor | UK |
| Laurent Eckert | Industry representative | France |
| Louise Gerbens | Health care professional: doctor | The Netherlands |
| Lucretia Adina Frasin | Health care professional: doctor | Italy |
| Luis Puig | Health care professional: doctor | Spain |
| Marie-Anne Morren | Health care professional: doctor | Belgium |
| Mariëlle Vermeulen | Secretary (minutes) | The Netherlands |
| Marijke van Hilten-Cornelisse | Health care professional: nurse | The Netherlands |
| Marit Saunes (MS1) | Health care professional: doctor | Norway |
| Marleen van der Stok (MS2) | Patient buddy and health care professional: nurse | The Netherlands |
| Michael Rudenko | Health care professional: doctor | UK |
| Paula Beattie | Health care professional: doctor | UK |
| Paula Williamson | Facilitator | UK |
| Phyllis Spuls | Health care professional: doctor | The Netherlands |
| Pieter van Nederkassel | Patient | Belgium |
| Pina Middelkamp-Hup | Health care professional: doctor | The Netherlands |
| Raquel Orfali | Health care professional: doctor | Brazil |
| Remco Böing | Industry representative | The Netherlands |
| Richard de Booij | Patient | The Netherlands |
| Richard Hudson | Industry representative | UK |
| Sandra Lawton | Health care professional: nurse | UK |
| Sanja Kezic | Non-clinical researcher | The Netherlands |
| Sanna Prinsen | Non-clinical researcher | The Netherlands |
| Sara Brown | Health care professional: doctor | UK |
| Simon van Leeuwen | Industry representative | The Netherlands |
| Valeria Aoki | Health care professional: doctor | Brazil |
| Willem Kouwenhoven | Patient | The Netherlands |

## Patiënt pre-meeting (Louise Gerbens)

Louise Gerbens (LG) welcomed everyone to Amsterdam and outlined the programme of today. She explained that the pre-meeting was held to empower patients and let them feel more comfortable to speak up. She emphasized that the opinion of patients is important and encouraged them to contribute and speak out loud.
Amanda Roberts (AR) asked whether the voting would be anonymous and asked if there is a certain amount of domain items that the TREAT Registry Taskforce would like to include. LG explained the voting is indeed anonymous and Carsten Flohr (CF) and LG explained that there is no certain amount needed but one should consider the feasibility of the registry.
A discussion was started by Pieter van Nederkassel (PN) regarding the manner of the voting. LG explained that the graphs of the previous eDelphi round 3 were to be showed with subsequently a discussion (if needed) and voting. She also explained that 'consensus in' was reached if less than 30% of participants disagreed. Richard de Booij (RB) summarized that today is about the domain items going 'in or out', not starting up the whole discussion again after the previous eDelphi rounds. CF added that Paula Williamson (PW) will be an independent facilitator to make sure there will be no steering from the TREAT Registry Taskforce. Phyllis Spuls (PS) emphasized again that this is why it is important for the patients to speak up if they think one of the items should get consensus in.
Anthea Wilson (AW) then asked what will happen to the items that will not get consensus in. CF explained they can still be used by the different centers, but that these will not be included in the core data set.

At the end of the presentation CF explained that the most important data of the registry will concern comparing effectiveness (including quality of life (QoL)), safety and cost-effectiveness of the different treatments. He explained "it is not about what you can do, but what must be done and is essential to be able to do data analysis." PS added that not all outpatient clinics will be able to gather all the data of the core set (feasibility). Registration of the core data set will be an improvement as now data are collected but not registered and shared.

## Welcome of all stakeholders (Phyllis Spuls)

PS welcomed everybody to the consensus meeting in Amsterdam in name of the TREAT Registry Taskforce. She declared it is very exciting that so many people from over the world are attending this meeting and supporting this project. She then asked different stakeholder groups to stand up to give a sense of balance of the attendees. The distribution was as follows: 6 patients, 6 nurses, 3 non-clinical researchers, 9 industry-representatives and 20 doctors. Regulatory body representatives were invited, but none responded or were able to come.

## The TREAT Registry Taskforce and TREAT eDelphi consensus exercise (aims, methods, instructions consensus meeting) (Phyllis Spuls and Louise Gerbens)

PS outlined the program for the day. She emphasized it is important for everyone to listen to the patients especially.

She gave several reasons why the TREAT Register is necessary; there are many patients with atopic eczema (AE) - severe AE as well -; there are not enough treatment options for severe AE; the existing treatments should be improved; the care for patients needs to be improved; there are still too many unanswered questions, especially from patients with comorbidities and from specific subgroups. She explained that data therefore need to be gathered on an international level to avoid data from getting lost and emphasized this registration should be done in the same way.

PS outlined to only vote an item 'in' if participants think an item is crucial to be collected. She explained that every center will be able to extend the core data set if they wish (e.g. for other research purposes) and that this meeting aims to reach consensus on the final core (i.e. essential) set of domains and domain items. Further this meeting is about 'what' to measure, not about 'how' to measure (e.g. instruments for measuring itch).

An explanation of the study design, methods and previous rounds followed.

PS encouraged all participants to ask for an explanation in case someone would vote 'unable to score' since everybody should be able to understand a voting item before voting. She emphasized one more time the meeting was about items going in or out, told one more time PW was independent and thanked LG for all her commitment.
CF asked every participant to fill out and hand in the conflict of interest form today and emphasized this is crucial for writing down the results and being able to present it.

LG explained how the meeting was organized and how the voting results would be displayed. Test voting was performed.

## Results after round 1-3, discussion and voting

LG presented the response rates of each eDelphi round and demographic data. Then the results after round 1-3 categorized by 'consensus in', 'no consensus and rated 'critical' by <50% in all groups (excluding regulatory body)' (i.e. no consensus and need no voting) and 'no consensus but rated 'critical' by ≥50% in at least 1 group (excluding regulatory body)' (i.e. no consensus and need voting) were presented by LG and PW.

### List of domains and domain items that have reached 'consensus in' after round 3

PW started with an introduction about herself and the way the voting would go. She explained she would start with the items that had already reached consensus in and encouraged all participants to remember 303 participants of round 3 already decided these items should be in (and 410 have participated and thought about these items). She therefore asked them to only suggest an item should go out if the participant had a very strong reason. Hereafter ten minutes were provided to have a look at the list and ask questions.

Several questions were asked that concerned the 'how' of the items instead of the 'what'. The group agreed these items would not be discussed today. A few questions were asked by AR and Amit Bodhani (AB) about systemic treatments. CF explained these are the kind of medications that are taken orally. Christian Apfelbacher (CA) wanted to know the specifics of the item 'evaluating TPMT level prior to azathioprine use' after which PS explained why it is important to test TPMT: Some patients have deficiency of TPMT because of genetic mutations. These people are at great risk of developing severe, potentially life-threatening bone marrow toxicity when treated with conventional doses of azathioprine or mercaptopurine. It is possible to test patients for TPMT activity before starting treatment with these drugs. Further it will only be measured when azathioprine will be started; i.e. it will be core only when applicable.

Laurent Eckert (LE) wanted to know why the items 'previous day hospital care treatments for AE' and 'previous hospitalization for AE' were both included. CA explained day hospital care only comprised one day after which the patient is discharged and hospitalization comprised several days.

Luis Puig (LP) stated that the item 'country' was not added to the list. He argued this was very important since different countries have different policies for admittance. PW explained it will be possible to see which country the data are from once the data are pulled from the different registries. CF added it would be interesting to see the different ways of treatment in different countries.

A discussion started considering the baseline versus follow up of physician and patient-reported. It was made clear that baseline was only to be performed once. Further there was a discussion about the items 'dermatology-specific QoL score' and 'AE-specific QoL score'. Carle Paul (CP) wanted to know if the intention was to measure all of these domains. CF and PS then explained indeed these were chosen to be 'in', and the intention was to register both QoL scores.

PW then asked the group if some of the items should not be in the core data set. PN suggested it might be better to give people some more flexibility; to make a selection of the core dataset based on local possibilities. It would also be possible to prioritize the items. The TREAT Registry Taskforce members explained again the core set definition; the items of the core set need to be measured at every center, but centers can always gather extra data.

CP asked what the definition of a flare according to HOME (Harmonising Outcome Measures for Eczema initiative) was going to be and stated that since it is hard to come with a widely accepted definition of a flare the group could consider getting the items 'reporting of disease control by physician' and 'reporting of disease control by patient' out of the core dataset. CF agreed with CP and explained no consensus by HOME had yet been reached and the TREAT Registry Taskforce was hoping the whole group would come up with a definition for this. Marit Saunes (MS1) then also suggested it might be good to drop this item. PW outlined this was a

'how' again instead of a 'what' and stated that even if the how is not known yet this shouldn't be a reason to remove the item from the core data set. She suggested not to start measuring this item until the 'how' was known. She then asked the group if anyone was in favor of dropping these two items. Richard Hudson (RH) stated a report of disease control would be very useful. PW asked if the patients wanted to contribute on this. Hillary Selles-Basford (HSB) stated this item was very important to keep in the core data set. PW concluded the item disease control would stay in the core data set, the 'how' would be a subject of research. CA then suggested collapsing the two items and considering the 'how' later. The group then voted on whether they agreed on combining the two items for reporting of disease control. Consensus was reached to combine these items (93% agreed).

The discussion continued for the items 'dermatology-specific QoL score' and 'AE-specific QoL score'. AR indicated there are too many questionnaires already for patients and asked why two questionnaires on QoL would be necessary (instead of just one). An explanation was given that the dermatology-specific QoL questionnaire would provide information that could be used for comparison with other dermatological diseases. CA added that the AE-specific QoL questionnaire on the other hand would be more specific for AE and to pick up a difference in data over time. CF then suggested to vote on having a QoL assessment rather than splitting it up in several questionnaires. AR agreed, but was concerned if this would still provide the same information.
CP stated the difference between the two questionnaires was very small so suggested combining the two would be a good option. Pina Middelkamp-Hup (PMH) added there are too many items already and suggested one questionnaire as well. CA then asked what the name of the new domain item would be. PW suggested to continue that discussion later. PS emphasized to bear in mind 410 people thought about these items already and separated it. PW then ended the discussion by asking if any of the items should be removed from the 'consensus in' list and suggested discussing the QoL questionnaires again at the end of the day (they were added to the list of discussion points). The group agreed not to drop any of the current items out of the 'consensus in' list apart from combining the 'reporting of disease control' items.

PMH wondered whether any of the attending dermatologists of the day would not be willing to gather all the core data after seeing all the items that are already voted in. PW then asked the group to raise their hands if someone was not willing to gather these data. None of the attending dermatologists did so.

AB wondered if there medical devices were considered, e.g. for the recording of scratching. PW reminded this was a 'how' again and proposed to add this to the list of discussion points.

LE suggested admission to the emergency room should be recorded as well in the core data set. Several participants agreed this would be a good item. PW therefore suggested to add this item to the list of discussion points that would be discussed at the end of the day if there would be time.

Fanneke Alkemade (AF) from Roche asked about registration of start and stop date of treatments. This is currently not included in the core data set. The members of the TREAT Registry Taskforce explained this will be registered.

### List of discussion points

- Combining and rename domain items 'dermatology-specific QoL' with 'AE-specific QoL'
- Usage of medical devices in recording scratching etc.
- Adding domain item admittance to the emergency room in the core data set

### List of domains and domain items that have reached no consensus and need no voting

PW started with asking the participants if they believed any of the items should be in the core data set and should be voted on by the group for considering inclusion.

HSB answered the home/social situation is very important for patients (e.g. considering stress) but also stated you don't want to tell this to everybody. CF then answered that this is indeed an important item for patients but perhaps less important for clinical practice and for the patient registry. HSB then asked if the difference between clinical practice and research data is indeed so clear and suggested combining social and marital history as an option.

Sanna Prinsen (SP) then made a general comment about the current and previous discussions. She worried that if too many changes were made this might undermine the voting from the previous eDelphi rounds. PW then suggested to leave the items 'social and marital status' for discussion at the end of the day if there would be time.

PW asked if there were any other comments. Valeria Aoki (VA) suggested 'blood testing for past/current tuberculosis (TBC)' might be important to keep in the core set. CF then explained this is different for different countries. It might be very important for Brazil but for others not that much. VA stated it still might be a good item because of the future biologicals. CF then reminded that it is part of the countries own clinical practice and concerning biologicals in trials the pharmaceutical companies are taking care of this. LP suggested this would be a good item for later discussion as well.

SP asked if there should be a vote that shows everyone is okay with keeping these items out. The group did not express the need for this. PW concluded that none of the items of this list will go in.

### List of discussion points

- Social and marital status: include in core data set?
- TBC testing: include in core data set?

## Voting on the 70 items that reached no consensus but need voting

PW started the discussion with stating the group needed to get to the end of the list by the end of the day.

### 1. Past AE treatments: previous structured education program for AE

PW started with asking if this item would add anything to the list of domains and domain items that are already included in the core data set. Simon van Leeuwen (SL) wanted to know what a structured program encompasses. CF explained this is a multidisciplinary program for patients in which they are taught how to use medication, how to recognize complications (e.g. infections) etc. PS added this item won't take a lot of time for recording (only yes/no, date).

AB wanted to know if there is any evidence these kind of programs have good results. CF confirmed this. Christian Vestergaard (CV) said he recognized the importance of the item and stated understanding AE is important as well but in his opinion this item was not important enough for the core data set. CA stated this item might be more important for the psychological aspect. He suggested a structured program would help in future medications. CF then wondered whether it would influence adherence. CP stated this item is a very important part of treatment and therefore should be in the core data set. Marie-Anne Morren (MM) added education is important when it comes in between treatments. It will positively influence the results and therefore it should be in. PN then stated he has been doing these programs. He found they are more helpful in psoriasis then in AE. Marijke van Hilten-Cornelisse (MH) told the group she voted the item in because she thought education is very important. As an example she gave the situation where a doctor decides a patient should start with topicals without the patient knowing how to use them.

A discussion then started about the specifics of a structured program. CV told the group every patient in Denmark has a meeting with a nurse for education which is not structured. He suggested this might give bias since the answer then had to be no but the patients received education in a different way. CF then suggested the answer might be changed to 'yes/no/not available'. HSB suggested information from patient organizations might be a good intermediate education. PW then explained a structured program would be more than this.

PW asked if anyone needed more clarification before starting with the voting. PS asked the group if it was clear what the difference is between a structured program and education.

The group voted: out.

### 2. Past AE treatments: prior participation in trials for AE

PW asked if anyone wanted to argue this item should go in the core data set. There was no response from the participants. CF then asked if any of the industry representatives wanted to say something about this item. FA stated the register will be for photo- and systemic treatments, therefore she found it not important to include in the core data set. CA then suggested people who have participated in trials might differ from patients who have never participated (adherence, being informed etc.). PW asked what the evidence for this is. CA explained there is no evidence and said it was an assumption he made. LP added the registry won't have any information from trials patients participated in. Therefore it could cause more noise than help.

The group voted: out.

### 3. Allergy test results: delayed contact hypersensitivity patch test

PW started with asking if there was anybody who would like more information about this item. CF explained this test showed whether you react to certain products; the results will be read a few days later (sometimes it takes 48 hours to show the results). He added this test is different from the skin prick (which takes 2-25 minutes) and blood test and this test is usually for chemical allergies.

PW then asked why the doctors do not want this item in the core data set (considering the graphs shown on the slide). Michael Rudenko (MR) then stated he would like this item in. PMH added she wanted it in as well, since patients that are difficult to treat in the daycare center have a high number of allergies. However, she added it might be redundant since the item 'contact allergies' is already included in the core data set. CV agreed on this. CP outlined this item might be difficult to control for quality. MM pleaded for not including the item since it is too difficult. She stated there are a lot of allergies and when the test is repeated in the stable phase of AE it does not show allergies.

A discussion then started about recording if the patient has been patch tested. PMH pleaded for adding the item 'has the patient been patch tested' since contact allergies now only includes a yes or no; it does not show whether the test is done or not. PS suggested to add several answers for the item 'contact allergies'; yes/no or not tested.

The group voted: out.

### 4. Allergy test results: atopy patch test

CF started by giving an additional explanation; this test is for allergens that are very common (house dust mite etc.), but there are some issues with the way it is performed. CA then asked what the added value of this test is. CF explained this could give additional information for the patients for avoidance of certain allergens. AR stated she strongly believes not all AE is the same. She therefore pleaded for subdividing eczema patients in different groups. By excluding this item she was afraid crucial information would be missed. CF then explained doctors are aware they should subdivide patients, but the test results are not that useful. Sara Brown (SB) added there is very little understanding of the results of these tests, therefore it is hard to interpret. CP agreed to this. PW suggested it will always be possible to add items in the future. RB wanted to know how many participants voted a 9 for this item, which appeared to be 3. Thereafter no more discussion followed.

The group voted: out.

### 5. Allergy test results: double-blind placebo-controlled food challenge

PW asked if anybody would like to add something or contribute and encouraged others to speak up as well. She also asked if any of the non-clinical researchers wanted to add something, which was not the case.

The group voted: out.

### 6. Allergy test results: skin prick testing to foods or aeroallergens

PN asked why the doctors voted this item out in the previous round. He wanted to know if it was because of the test being non-conclusive again. He was answered food allergies is already an item in the 'consensus in' list.

A suggestion was made that the answer could be divided in 'yes/no/not tested'.

The group voted: out.

### 7. Allergy test results: total IgE measurements in the past

PW asked if an explanation was needed. MR explained this test is usually used to predict false negative results in specific IgE.

A discussion followed on the usage of total and specific IgE. Some doctors pleaded the total IgE is not needed because it is not a specific marker and other doctors pleaded for voting it in because the specific IgE can be falsely positive with a high total IgE.

SP then suggested the IgE might be necessary for the new drugs that are coming; the response to these drugs might depend on the amount of IgE. CF then asked the doctors if they used the total IgE in their decisions. The group agreed this is not common practice. He then asked if it would be possible to divide the patients in groups with low, medium and high IgE; which would be possible but is not done yet. PMH also suggested the addition 'in the past' is a problem since IgE levels vary. She argued that is a reason not to add this item to the core data set.
PW emphasized again if it is not included in the core data set now this will still be possible in the future.

The group voted: out.

### 8. Allergy test results: past specific IgE measurements to foods or aeroallergens.

PW asked if anyone wanted to add something as the group just had the discussion on this topic, nobody made additional comments.

The group voted: out.

### 9. Chronic (inflammatory) co-morbidities: inflammatory bowel disease

The group voted: out.

### 10. Chronic (inflammatory) co-morbidities: rheumatoid arthritis

The group voted: out.

### 11. Chronic (inflammatory) co-morbidities: diabetes mellitus

The group voted: out.

### 12. Smoking history

PW asked if there were any arguments for this item definitely being out: no.

The group voted: out.

### 13. Alcohol intake

PW started with explaining most of the items that will be discussed will consider baseline and follow up items. She therefore explained she expected everyone would vote the same on those items. She then asked if anybody wanted to make an argument for the abovementioned item to stay out of the core data set. Nobody responded.

The group voted: out.

### 14. Current concomitant medication: allergic rhinoconjunctivitis medication

PS stated this item is redundant because of the item 'antihistamines, oral or topical' that is already included in the consensus in list. AR then pleaded this item does not cover all of the medications for rhinoconjunctivitis on which PS agreed.

The group voted: out (by just a small percentage).

### 15. Current concomitant medication: asthma medication

The group voted: out.

AR wondered whether the last two votes were potentially skewed because of the physicians as biggest group. Eric-Jan Dammers (ED) added it is very important for the pharmaceutical industry to know. Without this item the registry may not be of value. The pharmaceutical industry reports a treatment also effective if the costs of other comedication are going down. CP commented that dermatologists see the world through the skin and that research questions should be addressed. Does a treatment affect other treatments?

CF suggested to talk at the end of the day about allergy testing as patients found this important.

### 16. Current concomitant medication: use of complementary and alternative therapies

ED had the same argument as with item 15. CA liked to argue this since patients will search for other types of treatment when treatment does not work. AR commented that using complementary therapies is an option, but she wondered if it is also a marker of disengagement and dissatisfaction with the current treatment. She could not see the value of this item but added that if it is a surrogate marker for other therapies it has value.

The group voted: out.

### 17. Current concomitant medication: antidepressants

CA asked if there is any causal link known between AE therapies and depression? CF answered 'no'. AR commented that just because there is no evidence it does not mean therapies do not cause depression.

The group voted: out.

### 18. Current concomitant medication: sleep medication

PMH commented that sleep medication is important in the sense that AE patients might use more sleep medication which may say something about treatment effectiveness.

The group voted: out.

### 19. Baseline general AE questions: use of anti-bacterial soaps, washes, shampoos

The group voted: out.

### 20. Baseline general AE questions: number of baths and/or showers taken per week

PN commented that sea water has a good effect for his skin. In a non humid climate you have to use more topicals like lotions. He argued it therefore to be a valid item for the core data set.

The group voted: out.

### 21. Baseline general AE questions: current diet

The group voted: out.

### 22. Baseline general AE questions: contact with pets

The group voted: out.

### 23. Baseline general AE questions: exposures that trigger disease flares

The group voted: in.

### 24. Baseline general AE questions: factors that improve the disease

AR asked what these factors encompassed. PS and LG explained this is an additional item, added by a participant in round 1 without further explanation. PW commented that if an item is formulated too vague you should vote negatively. PW explained we would vote on the item with the explanation that it means anything that works for the individual patient.

The group voted: out.

### 25. Baseline general AE questions: episodes of skin infection

The group voted: in.

### 26. Baseline general AE questions: food and/or aeroallergen sensitization during childhood

CF commented that food allergies is already a domain included in the core data set. AM commented that a lot of children grow out of their food allergy. PMH commented that this item says sensitization, but it does not say anything about clinical symptoms. SP wanted more clarification about the item that is already in and this one. Jane Ravenscroft (JR) commented that a lot of people do not remember if they have been tested as a child.

The group voted: out.

### 27. Baseline general AE questions: coping strategies

PW asked if any of the patients would like to have this item included. PMH argued that the definition was too vague. LG explained this was an additional item, added in round 1 without further explanation. CA said it should encompass coping behavior. It could be an additional item in the future coping.

The group voted: out.

### 28. Baseline general AE questions: body image for winter summer differences in AE extent (drawing)

The group voted: out.

### 29. Baseline general AE questions: days lost from school/work

CA explained this is a measure of productivity loss and thus an indirect measure of costs which is very useful on society level. EJ agreed that for reimbursement purposes of drugs this is very important. SB argued that this item has not been well recorded in the past. A suggestion was made to add to the item 'due to atopic eczema'.

PN commented that a day lost from school or work is a step too far. A patient will find a solution in another way. AB commented that it is not just about the number of days lost. It is also about the productivity at work with your disease. RB commented that he was confused to whom this question is being asked. For him it means coping and QoL. AR added that this is somehow covered by the domain item QoL. Further every patient has its own way with dealing and from a patients' point of view this is not really relevant.

EJ argued that it is not the patients who will be reimbursed, so it means the new drugs will not be on the market. If we have not convince the market that it is useful we cannot bring the therapies on the market.

The group voted: in.

### 30. Baseline general AE questions: visits to other medical specialists

AB explained the same applies for this item point 29. CA asked why AB would expect these visits to go down if the AE is treated better. Marleen van der Stok (MS2) asked if this refers to a general or other eczema specialist. PS explained it is again an additional item and it was made clear we would vote on the item with other medical specialist being general specialist and not GPs.

The group voted: out.

### 31. Baseline physical examination: Fitzpatrick skin type

PMH told that in the AMC many patients with dark skin are seen and in her opinion there is a difference to how these patients respond to treatment, their distribution, type of AE, genotype and effect of genotype on treatment outcome. CF explained that in the context of phototherapy Fitzpatrick is important.

The group voted: in.

### 32. Baseline physical examination: weight and height for BMI calculation

It was asked if there is any evidence that correlates weight/height with the severity of AE. PS answered it might be important for the future, but not per se as a core item. PN argued it should go in, because it is easy to measure. CF explained it would only be useful from the pediatric perspective.

The group voted: out.

### 33. Baseline physical examination: blood pressure

The group voted: out.

### 34. Baseline physical examination: lymph node palpation

The group voted: out.

### 35. Baseline patient-reported generic quality of life score

EJ commented that reimbursement authorities would like to have the EQ-5D as questionnaire. After some discussion PW decided to vote on this item as generic QoL score.

The group voted: out.

PW and CA suggested to collapse the two QoL items of this morning. SB commented that QoL is very important and it seems critically important which questionnaire will be used. PW added we would come back to this at the end of the day and the 'how' should be decided at a later meeting. SB felt nervous making this major decision today and with the small group of today. PW suggested to park the discussion for today. CP asked if we should vote about all the different QoL questionnaires.

MS1 commented that in Norway medication is not reimbursed after having patients in these kind of registers. There might be differences in different countries. ED and RH commented that reimbursement decisions are made between several countries. EJ explained reimbursement is not a one time only thing, but it wo will be looked at again after a few years. AB commented that regulatory bodies were underrepresented at this meeting. PS explained we did contact them in the EU and US.

### 36. Baseline patient-reported satisfaction with AE care received

The group voted: in.

### 37. Baseline patient-reported psychological score

CA explained that e.g. the HADS questionnaire is a typical measure of psychological symptoms, often used in a clinical setting for psychiatric morbidity.

The group voted: out.

### 38. Baseline patient-reported impact of AE on the family

The group voted: in.

### 39. Baseline investigations: VZV immune status

CF explained chickenpox and the immune status is important before starting a biological. Getting chickenpox while using a biological is a risk.

The group voted: out.

### 40. Baseline investigations: pregnancy

CF explained this item is about the pregnancy test.

AR argued this item to be out: obviously you need to test before starting some of the therapies but she was not sure if this would be a core item. PS argued it should be in as a subgroup of patients may be included who want to become pregnant while using therapy. AW asked if it would not be better to perform clinical trials for this subgroup. PS explained the difficulties of performing trials in this group of patients.

CV commented that having a pregnancy test results may bias you to using certain treatments. PMH asked if pregnancy tests should be performed for phototherapies as well. CF answered that this was not thought about yet. Specification should be necessary (i.e. related only to systemic therapies or also phototherapies?).

The group voted: out.

### 41. Baseline investigations: monitoring P3NP in case of MTX use in adults

SP asked for clarification of the item. CP answered it is used to monitor the safety of MTX, however this is not a core business.

The group voted: out.

### 42. Baseline investigations: medical photographs to monitor disease extent

The group voted: out.

### 43. Baseline investigations: skin swabs for microbiome analyses

The group voted: out.

### 44. Baseline biorepository: blood for biomarkers

CF explained that biomarkers might help to distinguish different forms of the disease. CA added that we should collect blood for later research. PMH asked if we would also take blood from children. SB commented that proper storage is a lot of work. PW commented that it may be added with a specific research question.

The group voted: out.

### 45. Baseline biorepository: DNA for filaggrin analysis

PMH asked who would pay for this analysis and for the domain item 44. PW explained that this may be a domain item that might be added for a specific research question.

The group voted: out.

### 46. Baseline biorepository: biomaterials for a biorepository

The group voted: out.

AR commented that the most interested group were the patients. Patients are more interested in these kinds of data apparently.

### 47. Baseline management: main reasons for choosing specific treatment

CA asked for clarification if this was from the patient or doctor's perspective. PW argued if this item was not a 'how'. All decided that this is part of the 'how'.

The group voted: in.

### 48. FU general AE questions: 1B. Minimum FU frequency for registry data entry: 3 months

Clarification was asked. LG explained these questions are about frequency of data entry with several frequency options. PS explained the item in its full wording is 'once stable treatment dose has been reached'. CP argued that this is not core data. MS1 asked how long the registry will follow up patients. CF answered 5 to 10 years,

therefore it may be quite a burden to ask to register every 3 months. CF emphasize it is important to enter and register data at the same intervals in order to be able to compare data.

PS suggested these items may be too difficult to answer and not part of the core data set. PW suggested these items are a 'how' and not applicable for today's meeting. All agreed to not vote on these items.

*The above applies for:*

### 49. 1E

### 50. 2A

### 51. 2B

### 52. 2C

### 53. FU general AE questions: date of death and relation to AE
The group voted: in.

### 54. FU general AE questions: change in diagnosis after enrolment
The group voted: in.

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LG explained the rest of the domain items for voting are about follow up (FU). PW suggested to vote on these like the group did for baseline.

### 55. FU physical examination: weight and height for BMI calculation
The group voted: out.

### 56. FU physical examination: body temperature
The group voted: out.

### 57. FU physical examination: chest auscultation
The group voted: out.

### 58. FU physical examination: lymph node palpation
The group voted: out.

### 59. FU patient-reported generic QoL score
The group voted: in.

PW commented that we need to come back to this one at the end of the day (QoL issue).

### 60. FU patient-reported psychological score
The group voted: out.

### 61. FU patient-reported impact of AE on the family
The group voted: in.

### 62. FU social-emotional status (open question: how are you doing?)
AR commented that this is a very important question that gives a good impression. From a patient's point of view it is clear to include it. AW commented that it is different saying things than filling in a questionnaire. AB commented who this item is different from QoL scores. CA explained that some more generic QoL questionnaires ask this. However as a single item it is too difficult to measure. Further it is a 'how'. PMH commented that this question opens emotions in patients and it should always be asked by doctors. However in her opinion it should not be in a registry. PN suggested to make a scale for this question (range 0-5) in order to make the question more objective.

The group voted: out.

### 63. FU investigations: B. minimum frequency of safety investigations: 8 weeks
See above: All agreed to not vote on these items (63-65).

### 64. FU investigations: D. minimum frequency of safety investigations: 12 weeks

### 65. FU investigations: F. minimum frequency of safety investigations: 16 weeks

### 66. FU investigations: medical photographs to monitor disease extent
The group voted: out.

### 67. FU investigations: skin swabs for microbiome analyses
The group voted: out.

### 68. FU investigations: test for internal cortisol production
The group voted: out.

### 69. FU biorepository: blood for biomarkers
The group voted: out.

### 70. FU biorepository: biomaterials for a biorepository
The group voted: out.

## List of discussion points
1. Obvious domain item: eosinophilic eosophagitis, should this be out of the obvious list? (suggested by CP)
2. Combining and rename domain items 'dermatology-specific QoL' with 'AE-specific QoL'
3. Usage of medical devices in recording scratching etc.
4. Adding domain item admittance to the emergency room in the core data set
5. Social and marital status: include in core data set? Rename as 'home situation'? Does it belong to the domain 'demographics'?
6. Concomitant medication: asthma and allergic rhinoconjunctivitis out, but needed for reimbursement
7. TBC testing: include in core data set?
8. Contact allergies (included in core data set): except for performed yes/no, maybe include option what kind of test (e.g. patch test)
9. Allergy domain items: a few are not included, but patients voted 'in'. Maybe reconsider?
10. Coping strategies/behavior: possible additional item for the future
11. General AE questions: days lost from school/work: consider adding 'due to AE'
12. Baseline biorepository: blood for biomarkers and DNA for filaggrin analysis: maybe items for a specific research question and therefore possible additional items for the future
13. Baseline investigations: pregnancy: out, but should this not be in? (suggested by PS)

## Discussion point 2

It was discussed that after round 3 303 participants decided to include both 'dermatology-specific QoL' and 'AE-specific QoL' questionnaires in the core data set. As discussed previously it could be an option to combine these two into one domain. PS commented that there need to be very strong arguments to overrule the eDelphi results.

MS2 asked if the HOME initiative has any recommendations already about QoL questionnaires. CA explained that at the moment research is still conducted and no consensus has been reached. HOME recommendation is that it should be specific though. Generic questionnaires do not have this. CA said that 410 participants decided these two to be included. However patients have a strong voice and they said earlier that the amount of

questionnaires is a lot. One could argue therefore that the two questionnaires could be combined and a generic QoL questionnaire is included as well for reimbursement purposes.

PW suggested to vote on combining the two specific QoL questionnaires. The group agreed.

### 71. Do you want to collapse the domains of patient-reported dermatology specific QoL and AE-specific QoL as skin-specific QoL?

The group voted: in/yes.

PS asked if the group also wanted to have a vote for baseline generic QoL questionnaire, as the FU version was included in the core data set.

SP commented that there is a need to have an instrument that is tested in AE patients otherwise you cannot rely on the outcome. CA commented on this that we must not think about the measurement instrument at the moment.

### 72. Do you want to include baseline patient-reported generic QoL score in the core data set?

The group voted: in.

The meeting was closed by PW, PS and CF.

The group and TREAT Registry Taskforce members decided it is necessary to have a smaller meeting to decide about the 'how to measure'. The members promised to plan this meeting.