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Appendix 1

Table 1. Profile of the Consortium Members at Each Stage of the Development of SISAQOL Recommendations

	Kick-off meeting *Jan 2016* (*N* = 26)	Strategic meeting *Jan 2017* (*N* = 29)	Working groups May 2017 – August 2018			Recom-mendations meeting *Sept 2018* (*N* = 31)	All[1] (*N* = 41)
			Research objectives (*N* = 26)	Statistical methods (*N* = 18)	Missing data (*N* = 10)		
Background							
Academia	7	10	9	4	1	7	14
Non-Profit	8	6	6	6	7	10	10
Government	3	5	7	5	1	8	8
Industry	4	4	2	2	1	3	4
Health Care	3	3	2	1	0	2	3
Other	1	1	0	0	0	1	2
Role[2]							
Researcher/health related academic	15	16	17	10	5	16	24
Expert advisor on PROs	8	11	9	4	3	8	14
Statistician	9	9	7	12	4	10	12
Clinician/clinical professor	4	6	6	1	1	5	10
Trials Methodologist	7	8	6	7	3	6	9
Policy maker/regulator	2	3	4	3	1	5	5
Industry representative	3	3	2	1	1	2	3
(Health) psychologist	2	3	3	2	1	2	3
Health Economist	1	1	0	0	0	2	2
Reviewer	1	2	1	1	0	2	2
Patient representative	0	1	1	0	0	1	1
Journal Editor	1	1	0	0	1	1	1
Country							
Australia	0	0	1	1	0	0	1
Austria	0	0	1	0	0	0	1
Belgium	7	4	5	5	5	7	8
Canada	0	1	2	0	1	2	2
Denmark	1	1	1	0	0	1	1

[1] Membership list as on September 24th, 2018 (Recommendations meeting)

[2] Consortium members could have up to three roles

France	2	1	1	1	0	0	1
Germany	3	4	1	2	0	4	4
Portugal	0	0	0	0	0	0	1
Sweden	1	1	0	1	0	1	1
The Netherlands	1	2	1	0	0	1	2
UK	5	6	4	1	1	7	7
USA	6	9	9	7	3	8	12

Table 2: Each Working Group's Process in Developing Proposed Statements for the SISAQOL Meeting

<table>
<tr><td></td><td colspan="4">Working Groups (WG)</td></tr>
<tr><td>Dates</td><td>Research Objectives</td><td>Statistical Methods</td><td>Standardizing Terms Related to Missing Data</td><td>General Handling of Missing Data</td></tr>
<tr><td colspan="5">2017</td></tr>
<tr><td>May</td><td colspan="4">WebEx discussions

- Strategy kick-off WebEx meeting for all working group (WG) members
- Presentation and discussion of content, problem description and next steps for each WG</td></tr>
<tr><td>June

July

August</td><td rowspan="2">- Preparation of the initial draft of taxonomy of research objectives
- Preparation of survey to standardize objectives: improvement, stable state and worsening</td><td rowspan="2">- Preparation of survey to list recommended statistical features for PRO/HRQOL analysis</td><td rowspan="2">- Preparation of survey on various definitions related to missing data: intent-to-treat (ITT), modified intent-to-treat (mITT), completion and compliance rates</td><td rowspan="4">- Preparation for Monte-Carlo simulations to answer the question "how much missing data is too much"</td></tr>
<tr><td>September

October</td><td rowspan="3">- WG members provided comments and feedback on the draft taxonomy of research objectives
- WG members responded to survey on standardizing objectives</td></tr>
<tr><td>November

December</td><td>- WG members responded to survey on list of recommended statistical features for PRO analysis</td><td>- Consortium members responded to survey on definitions for these terms related to missing data</td></tr>
<tr><td colspan="5">2018</td></tr>
<tr><td>January</td><td colspan="4">WebEx discussions (taxonomy of research objectives)</td></tr>
</table>

<table>
<tr><td></td><td colspan="3">- Presentation of comments on taxonomy of research objectives
- Presentation of survey responses on standardizing research objectives: improvement, stable state and worsening
- Agreement on updated taxonomy of research objectives</td></tr>
<tr><td>February</td><td rowspan="3">- Preparation of findings for recommendations meeting</td><td colspan="2">WebEx discussions

- Presentation of survey results on essential and highly desirable statistical properties for PRO analysis
- Agreement on essential and highly desirable statistical properties for PRO analysis
- Presentation of survey results on standardizing statistical terms to statistics methods WG</td></tr>
<tr><td>March</td><td colspan="2">WebEx discussions

- Next steps: Work method for recommending appropriate statistical methods for each research objective based on the essential/highly desirable statistical properties
- Presentation of Monte Carlo simulations for missing data thresholds
- Standardized case report forms for reasons for missing data</td></tr>
<tr><td>April</td><td>- Literature review to evaluate statistical methods for each objective based on the properties list
- WG members feedback on evaluation of statistical methods</td><td>- Literature review on definitions of missing data</td><td>- Collection of case report forms for missing data reasons from SISAQOL members
- Running of final Monte Carlo Simulations</td></tr>
<tr><td>May</td><td colspan="3">WebEx discussions: status update from each working group</td></tr>
</table>

<table>
<tr><td>June</td><td rowspan="3">- Preparation of findings for recommendations meeting</td><td colspan="2">WebEx Discussions

- Proposal of recommended appropriate statistical methods for each research objective
- Presentation of varying definitions of missing data</td><td rowspan="3">- Consortium members responded to survey on reasons for non-completion based on collected case report forms

- Development of missing data recommendations

- Preparation of findings for recommendations meeting</td></tr>
<tr><td>July</td><td>- Preparation of findings for recommendations meeting</td><td>- Preparation of findings for recommendations meeting</td></tr>
<tr><td>August</td><td></td><td></td></tr>
<tr><td>September</td><td colspan="4">SISAQOL recommendations meeting: Ratify proposed statements from each working group</td></tr>
</table>