ICHOM

International Consortium for
Health Outcomes Measurement

INFLAMMATORY ARTHRITIS
DATA COLLECTION REFERENCE GUIDE

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Measuring
results
that matter

Inflammatory
Arthritis

ICHOM

INFLAMMATORY ARTHRITIS

We are thrilled that you are interested in measuring outcomes for your patients with inflammatory arthritis according to ICHOM standards. It is our hope that this Reference Guide will facilitate the process of implementing our Standard Set and ensure collection of comparable data for global benchmarking and learning.

Introducing ICHOM and the Reference Guide

ICHOM brings together patient representatives, clinician leaders, and registry leaders from all over the world to develop Standard Sets, comprehensive yet parsimonious sets of outcomes and case-mix variables we recommend all providers track.

Each Standard Set focuses on patient-centered outcomes, and provides an internationally-agreed upon method for measuring each of these outcomes. We do this because we believe that standardised outcomes measurement will open up new possibilities to compare performance globally, allow clinicians to learn from each other, and rapidly improve the care we provide our patients.

Our Standard Sets include initial conditions and risk factors to enable meaningful case-mix adjustment globally, ensuring that comparisons of outcomes will take into account the differences in patient populations across not just providers, but also countries and regions. A comprehensive data dictionary, as well as scoring guides for patient-reported outcomes is included in the appendix.

Our aim is to make Standard Sets freely accessible to healthcare institutions worldwide to begin measuring, and ultimately benchmark the outcomes they achieve. In order to have a guide from which we can benchmark outcomes, we require feedback from initial implementation efforts. As such, this Reference Guide may undergo revisions on a regular basis. If you have any suggestions or would like to provide feedback, please contact implement@ichom.org

Working Group Members for Inflammatory Arthritis

The following individuals dedicated both time and expertise to develop the ICHOM Standard Set for Inflammatory Arthritis in partnership with ICHOM, under the leadership of Prof. Mart van de Laar and Dr. Harald Vonkeman, Rheumatologists at the University of Twente, Netherlands.

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Supporting Organisations

The Inflammatory Arthritis Standard Set is made possible only through the support of the following organisations.

Thank you.

Conditions and Treatment Approaches Covered for Inflammatory Arthritis

All treatment options and the following conditions are covered by our Standard Set.

Conditions	Rheumatoid Arthritis | Psoriatic Arthritis Ankylosing Spondylitis | Juvenile Idiopathic Arthritis

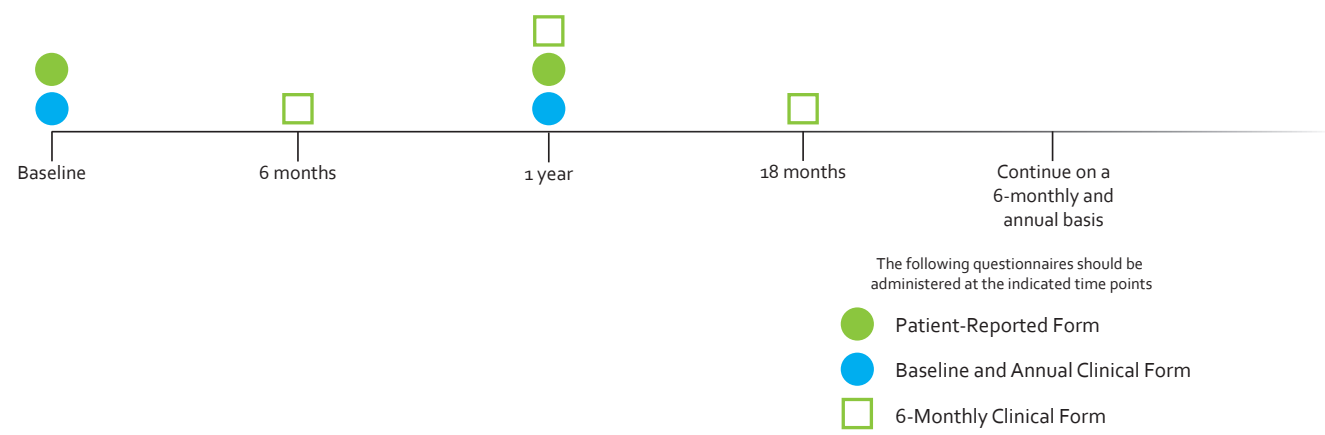# ICHOM Standard Set for Inflammatory Arthritis Overview

Case-Mix Variables

Patient Population	Measure	Supporting Information	Timing	Data Source
Demographic Factors				
All patients	Age	Age in years	Baseline	Patient-reported
	Sex	Sex at birth		
	Education level	Highest attained education		
Baseline Clinical Status				
All patients	Smoking	N/A	Baseline	Patient-reported
Baseline Clinical Status				
All patients	Comorbidities	N/A	Baseline	Clinical
	Physician-reported inflammatory arthritis diagnosis		Baseline and annually	
	Disease duration		Baseline	
RA & JIA patients	Immunological	Rheumatoid factor and ACPA	Baseline	Clinical or Administrative data

Outcomes overview

Patient Population	Measure	Supporting Information	Timing	Data Source
Patient-Reported Outcomes				
All patients	Pain	Measured on a standardised reporting metric	Baseline and annually	Patient-reported
	Fatigue			
	Activity limitation			
	Overall emotional and physical health impact			
	Work/school/ housework ability and productivity	Tracked via WPAI tool		
Treatment-Specific				
All patients	Serious adverse events	Categorised by FDA guidelines	Baseline and annually	Clinical
	Response/ remission	Achievement of treatment target		
	Inflammatory disease activity	N/A	Baseline and 6-monthly if disease is active; Baseline and annually if in remission	

Follow-Up Timeline and Sample Questionnaires

The following timeline illustrates when Standard Set variables should be collected from patients, clinicians, and administrative sources. Links to the sample questionnaires may be found in the legend below.

| Baseline | 6 months | 1 year | 18 months | Continue on a 6-monthly and annual basis |

The following questionnaires should be administered at the indicated time points

- 🟢 Patient-Reported Form
- 🔵 Baseline and Annual Clinical Form
- ⬜ 6-Monthly Clinical Form

Collecting Patient-Reported Outcome Measures

The ICHOM inflammatory arthritis working group recommends that each of the patient-reported outcome domains listed in the table below are measured using one PROM tool per outcome domain. For each of the PROM outcome domains included in the ICHOM inflammatory arthritis Standard Set, users can choose one instrument from the selection of PROMs listed in the table below. Scores on these instruments have been linked to a standardised reporting metric, so that outcomes can be compared between users of the set that have chosen to use a different instrument with their patients. To obtain linked scores, visit: http://tihealthcare.nl/en/expertise/common-metrics

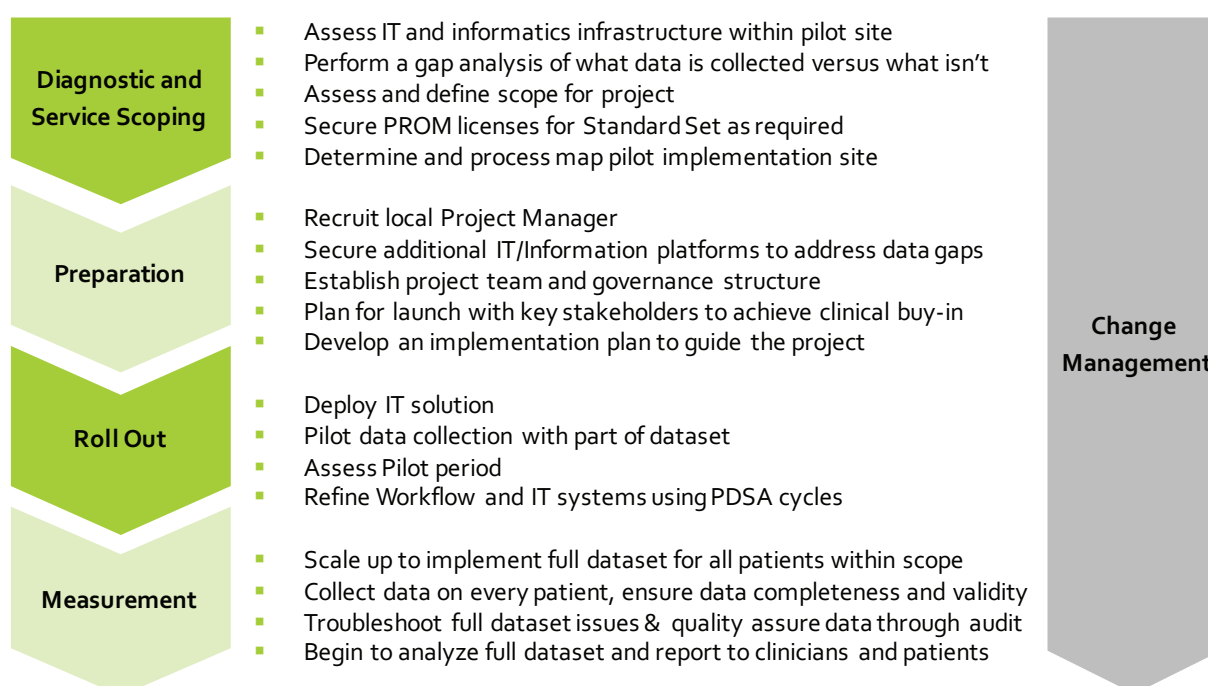| Patient-reported outcome domain	Inflammatory arthritis survey used	Population	Licensing Information	Link to questionnaire
Pain	Numerical rating scale	Adult/paediatric	Free	Refer to Reference Guide Appendix
	Visual analogue scale			
	SF-36 bodily pain	Adult	Licensing fee may apply	
	RAND bodily pain		Free	http://bit.ly/RSF-36
	PROMIS pain interference		Use of short form is free	http://bit.ly/PIAdult
	PedsQL 3.0 Arthritis module pain and hurt	Paediatric	Licensing fee applies, Free for non-funded academic research	http://bit.ly/PedsAM
Fatigue	Numerical rating scale	Adult/paediatric	Free	Refer to Reference Guide Appendix
	Visual analogue scale			
	FACIT-F	Adult	Free for English version	http://bit.ly/FACIT-F
	BRAF-MDQ		Free	http://bit.ly/BRAFIA
	PROMIS fatigue		Use of short form is free	http://bit.ly/PAFatigue
	PedsQL4.0 SF 15 Generic Core Scales Fatigue	Paediatric	Licensing fee applies http://bit.ly/	http://bit.ly/PedsQLFatigue
Activity limitation	HAQ-II	Adult	Free	http://bit.ly/HAQIIIA
	HAQ-DI			http://bit.ly/HAQ-DI
	MD-HAQ			http://bit.ly/IAMDHAQ
	PROMIS Physical Function		Use of short form is free	http://bit.ly/PFAdult
	BASFI		Free	http://bit.ly/IABASFI
	C-HAQ	Paediatric		http://bit.ly/C-HAQ
	JAMAR			http://bit.ly/JAMAR
Overall emotional and physical health impact	Numerical rating scale	Adult/paediatric	Free	Refer to Reference Guide Appendix
	Visual analogue scale			
	EQ-5D-5L	Adult	Licensing fee may apply	http://bit.ly/EQ5D5L
	SF-6D			http://bit.ly/SF-6D
	RAID		Free	http://bit.ly/RAIDIA
	PSAID			http://bit.ly/PSAIDCP
	CIHQ	Paediatric		
Work/school/housework ability and productivity	WPAI	Adult	Free	http://bit.ly/RAWPAI
	PedsQL4.0 SF 15 Generic Core Scales School Functioning	Paediatric	Licensing fee may apply	http://bit.ly/PedsQOL

The Growing ICHOM Community

There is a growing community of healthcare providers implementing the ICHOM Standard Sets. To support your organisation in implementing the set and the measurement of outcomes data, we have outlined a framework to guide the implementation and reporting of patient-centered outcomes. For further information or to enquire about Implementation support offered by ICHOM, please contact the Implementation team: implement@ichom.org

Implementation framework:
The framework below, outlines the structured process to guide the implementation of an ICHOM Standard Set at your organisation. Typically an implementation project takes 9 months to complete.

Diagnostic and Service Scoping
- Assess IT and informatics infrastructure within pilot site
- Perform a gap analysis of what data is collected versus what isn't
- Assess and define scope for project
- Secure PROM licenses for Standard Set as required
- Determine and process map pilot implementation site

Preparation
- Recruit local Project Manager
- Secure additional IT/Information platforms to address data gaps
- Establish project team and governance structure
- Plan for launch with key stakeholders to achieve clinical buy-in
- Develop an implementation plan to guide the project

Roll Out
- Deploy IT solution
- Pilot data collection with part of dataset
- Assess Pilot period
- Refine Workflow and IT systems using PDSA cycles

Measurement
- Scale up to implement full dataset for all patients within scope
- Collect data on every patient, ensure data completeness and validity
- Troubleshoot full dataset issues & quality assure data through audit
- Begin to analyze full dataset and report to clinicians and patients

Change Management

ICHOM is also able to support organisations with a variety of support models:

1. Capacity building – direct advisory support
2. Community models – supporting a community of providers in outcomes adoption and innovation
3. Education – workshops and short courses regarding Value Based Healthcare and implementation skills

Translating the Set Tools:
PROMs within the ICHOM Sets are available in a number of languages. To check the availability of translations, we advise contacting the Tool authors directly to obtain and translate the PROM surveys into your desired language. To independently translate PROM surveys, we recommend following the 10 steps outlined below:*[1]

Step 1	Preparation	Initial work carried out before the translation work begins
Step 2	Forward Translation	Translation of the original language, also called source, version of the instrument into another language, often called the target language
Step 3	Reconciliation	Comparing and merging more than one forward translation into a single forward translation
Step 4	Back Translation	Translation of the new language version back into the original language
Step 5	Back Translation Review	Comparison of the back-translated versions of the instrument with the original to highlight and investigate discrepencies between the original and the reconciled translation, which is then revised in the process of resolving the issues
Step 6	Harmonization	Comparison of back translations of multiple language versions with each other and the original instrument to highlight discrepencies between the original and its derivative translations, as well as to achieve a consistent approach to translation problems
Step 7	Cognitive Debriefing	Testing the instrument on a small group of relevant patients or lay people in order to test alternative wording and to check understandability, interpretation, and cultural relevance of the translation
Step 8	Review of Cognitive Debriefing Results and Finalisation	Comparison of the patients' or lay persons' interpretation of the translation with the original version to highlight and amend discrepencies
Step 9	Proofreading	Final review of the translation to highlight and correct any typographic, grammatical or other errors
Step 10	Final Report	Report written at the end of the process documenting the development of each translation

*These ten steps follow the ISPOR Principles of Good Practice:The Cross-Cultural Adaptation Proccess for Patient-Reported Outcomes Measures [1] Wild, D., Grove, A., Martin, M., Eremenco, S., McElroy, S., Verjee-Lorenz, A., et al. (2005). Principles of good practice for the translation and cultural adaptation process for patient-reported outcomes (PRO) measures: Report of the ISPOR task force for translation and cultural adaptation. Value in Health, 8(2), 94–104. doi:10.1111/j.1524-4733.2005.04054.x.

For any questions about implementation please contact us at: implement@ichom.org

Appendix

Introduction to the Data Dictionary

This data dictionary is designed to help you measure the ICHOM Inflammatory Arthritis Standard Set as consistently as possible to the Working Group recommendation. ICHOM is actively preparing for benchmarking efforts based on this data, and all data submitted for comparisons will need to be transformed into the following data structure if not already structured as such. **We are happy to provide an Excel version of this data dictionary for technical use.**

Please timestamp all variables. Some Standard Set variables are collected at multiple timepoints, and we will ask you to submit these variables in a concatenated VARIABLEID_TIMESTAMP form for future analyses. For example, VARIABLEID_BASE (baseline); VARIABLEID_6MO (6 month follow-up); VARIABLEID_1YR (1 year follow-up), etc.

Case-Mix Variables

Variable ID:	N/A
Variable:	Patient ID
Definition:	Indicate the patient's medical record number
Supporting Definition:	This number will not be shared with ICHOM. In the case patient-level data is submitted to ICHOM for benchmarking or research purposes, a separate ICHOM Patient Identifier will be created and cross-linking between the ICHOM Patient Identifier and the medical record number will only be known at the treating institution
Inclusion Criteria:	All patients
Timing:	On all forms
Data Source:	Administrative or clinical
Type:	Numerical
Response Options:	According to institution

Demographic Factors

Variable ID:	AGE
Variable:	Age
Definition:	Indicate the patient's age
Supporting Definition:	Recorded as year of birth
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Patient-reported
Type:	Date by YYYY
Response Options:	YYYY

Variable ID:	SEX
Variable:	Sex at birth
Definition:	Indicate the patient's sex at birth
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Patient-reported
Type:	Single answer
Response Options:	1 = Male
	2 = Female
	999 = Unknown

Variable ID:	SOCIO
Variable:	Education level
Definition:	Highest attained education
Supporting Definition:	Level of schooling defined in each country according to the International Standard Classification of Education
Inclusion Criteria:	All patients

Timing:	Baseline and ongoing
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = None
	1 = Primary
	2 = Secondary
	3 = Tertiary

Baseline Characteristics

Variable ID:	SMOKING
Variable:	Smoking status
Definition:	Indicate the patient's category
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Never
	1 = Former
	2 = Current

Baseline Condition Factors

Variable ID:	BASEHBP
Variable:	High blood pressure
Definition:	Indicate whether the patient has hypertension and/or uses antihypertensive medication
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Clinician
Type:	Single answer
Response Options:	0 = No
	1 = Yes
	999 = Unknown
Variable ID:	BASEAMI
Variable:	Myocardial infarction
Definition:	Indicate whether the patient has had a myocardial infarction
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Clinician
Type:	Single answer
Response Options:	0 = No
	1 = Yes
	999 = Unknown
Variable ID:	BASESTR
Variable:	Stroke (excluding transient ischemic attacks)
Definition:	Indicate whether the patient has had a stroke (excluding transient ischemic attacks)
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Clinician
Type:	Single answer
Response Options:	0 = No
	1 = Yes

	999 = Unknown
Variable ID:	BASEOHD
Variable:	Other heart disease
Definition:	Indicate whether the patient has any other heart disease
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Clinician
Type:	Single answer
Response Options:	0 = No
	1 = Yes
	999 = Unknown
Variable ID:	BASECLD
Variable:	Chronic lung disease
Definition:	Indicate whether the patient has chronic lung disease
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Clinician
Type:	Single answer
Response Options:	0 = No
	1 = Yes
	999 = Unknown
Variable ID:	BASEDM
Variable:	Diabetes mellitus
Definition:	Indicate whether the patient has diabetes mellitus
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Clinician
Type:	Single answer
Response Options:	0 = No
	1 = Diabetes mellitus type 1
	2 = Diabetes mellitus type 2
	999 = Unknown
Variable ID:	BASEMALIG
Variable:	Malignancies
Definition:	Indicate whether the patient has any malignancies
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Clinician
Type:	Single answer
Response Options:	0 = No
	1 = Yes
	999 = Unknown
Variable ID:	BASEDEP
Variable:	Depression
Definition:	Indicate whether the patient has depression
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Clinician
Type:	Single answer
Response Options:	0 = No
	1 = Yes
	999 = Unknown

Variable ID:	BASEFRAC
Variable:	Fracture
Definition:	Indicate whether the patient has a fracture
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Clinician
Type:	Single answer
Response Options:	0 = No
	1 = Yes
	999 = Unknown

Variable ID:	BASEULCER
Variable:	Stomach ulcer
Definition:	Indicate whether the patient has stomach ulcers
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Clinician
Type:	Single answer
Response Options:	0 = No
	1 = Yes
	999 = Unknown

Variable ID:	BASESTOM
Variable:	Stomach problem
Definition:	Indicate whether the patient has stomach problems
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Clinician
Type:	Single answer
Response Options:	0 = No
	1 = Yes
	999 = Unknown

Variable ID:	BASEOB
Variable:	Obesity
Definition:	Indicate whether the patient is obese
Supporting Definition:	Obesity is defined as a BMI ≥30
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Clinician
Type:	Single answer
Response Options:	0 = No
	1 = Yes
	999 = Unknown

Variable ID:	IA_DIAG
Variable:	Inflammatory arthritis diagnosis
Definition:	Indicate the current diagnosis/diagnoses of inflammatory arthritis
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and annually
Data Source:	Clinician
Type:	Multiple answer
Response Options:	1 = Rheumatoid arthritis
	2 = Spondyloarthritis
	3 = Psoriatic arthritis
	4 = Juvenile idiopathic arthritis

Variable ID:	DISDUR

Variable:	Disease duration
Definition:	Indicate the year of inflammatory arthritis diagnosis
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Clinician
Type:	Date by YYYY
Response Options:	YYYY
Variable ID:	IMM_RF
Variable:	Rheumatoid factor
Definition:	Indicate the presence of rheumatoid factor
Supporting Definition:	N/A
Inclusion Criteria:	If "1 = Rheumatoid arthritis" or "4 = Juvenile idiopathic arthritis" to IA_DIAG
Timing:	Baseline
Data Source:	Clinician
Type:	Single answer
Response Options:	0 = Negative
	1 = Positive
	999 = Unknown
Variable ID:	IMM_ACPA
Variable:	ACPA
Definition:	Indicate the presence of anti-citrullinated protein antibodies (ACPA)
Supporting Definition:	N/A
Inclusion Criteria:	If "1 = Rheumatoid arthritis" or "4 = Juvenile idiopathic arthritis" to IA_DIAG
Timing:	Baseline
Data Source:	Clinician
Type:	Single answer
Response Options:	0 = Negative
	1 = Positive
	999 = Unknown

Outcomes

Patient-Reported Outcomes

Questions from the PROMs below represent the shortest combination of instruments to measure in the Standard Set, according to standardised reporting metrics. For more information on using PROMs to measure patient-reported outcomes, please see page 6.

Variable ID:	PROMCHOICE_PAIN
Variable:	PROM Choice - Pain
Definition:	Which Patient-Reported Outcome Measure are you using to measure pain?
Supporting Definition:	Choose one from:
	Numerical Rating Scale
	Visual Analogue Scale
	SF-36 Bodily Pain
	PROMIS Pain Interference
	PedsQL Pain and Hurt
Inclusion Criteria:	All patients
Timing:	Baseline and annually
Data Source:	Patient-reported
Type:	Single answer
Response Options:	1 = Numerical Rating Scale
	2 = Visual Analogue Scale
	3 = SF-36 Bodily Pain
	4 = PROMIS Pain Interference
	5 = PedsQL Pain and Hurt
Variable ID:	PAIN_NRS
Variable:	Pain Numerical Rating Scale

Definition:	Circle the number that best describes the pain you felt due to your arthritis during the last week.
Supporting Definition:	0 = None
	10 = Extreme
Inclusion Criteria:	If "1 = NRS" to PROMCHOICE_PAIN
Timing:	Baseline and annually
Data Source:	Patient-reported
Type:	Numerical
Response Options:	Numerical value between 0 and 10

Variable ID:	PROMCHOICE_FAT
Variable:	PROM Choice - Fatigue
Definition:	Which Patient-Reported Outcome Measure are you using to measure fatigue?
Supporting Definition:	Choose one from:
	Numerical Rating Scale
	Visual Analogue Scale
	FACIT-F
	BRAF
	PROMIS Fatigue
	PedsQL4.0 Fatigue Total Score
Inclusion Criteria:	All patients
Timing:	Baseline and annually
Data Source:	Patient-reported
Type:	Single answer
Response Options:	1 = Numerical Rating Scale
	2 = Visual Analogue Scale
	3 = FACIT-F
	4 = BRAF
	5 = PROMIS Fatigue
	6 = PedsQL4.0 Fatigue Total Score

Variable ID:	FATIGUE_NRS
Variable:	Fatigue Numerical Rating Scale
Definition:	Circle the number that best describes how much fatigue you felt due to your arthritis during the last week.
Supporting Definition:	0 = No fatigue
	10 = Totally exhausted
Inclusion Criteria:	If "1 = NRS" to PROMCHOICE_FAT
Timing:	Baseline and annually
Data Source:	Patient-reported
Type:	Numerical
Response Options:	Numerical value between 0 and 10

Variable ID:	PROMCHOICE_ACT
Variable:	PROM Choice - Activity limitations
Definition:	Which Patient-Reported Outcome Measure are you using to measure activity limitations?
Supporting Definition:	Choose one from:
	HAQ-II
	HAQ-DI
	MHAQ
	MD-HAQ
	PROMIS Physical Function
	BASFI
	C-HAQ
	JAMAR
Inclusion Criteria:	All patients
Timing:	Baseline and annually
Data Source:	Patient-reported
Type:	Single answer

Response Options:	1 = HAQ-II
	2 = HAQ-DI
	3 = MHAQ
	4 = MD-HAQ
	5 = PROMIS Physical Function
	6 = BASFI
	7 = C-HAQ
	8 = JAMAR

Variable ID:	HAQ2_Q01
Variable:	HAQ-II Question 1
Definition:	We are interested in learning how your illness affects your ability to function in daily life. Place an X in the box which best describes your usual abilities OVER THE PAST WEEK:
	Are you able to:…Stand up from a straight chair?
Supporting Definition:	N/A
Inclusion Criteria:	If "1 = HAQ-II" to PROMCHOICE_ACT
Timing:	Baseline and annually
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Without Any Difficulty
	1 = With Some Difficulty
	2 = With Much Difficulty
	3 = Unable To Do

Variable ID:	HAQ2_Q02
Variable:	HAQ-II Question 2
Definition:	Are you able to:… Walk outdoors on flat ground?
Supporting Definition:	N/A
Inclusion Criteria:	If "1 = HAQ-II" to PROMCHOICE_ACT
Timing:	Baseline and annually
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Without Any Difficulty
	1 = With Some Difficulty
	2 = With Much Difficulty
	3 = Unable To Do

Variable ID:	HAQ2_Q03
Variable:	HAQ-II Question 3
Definition:	Are you able to:… Get on/off toilet?
Supporting Definition:	N/A
Inclusion Criteria:	If "1 = HAQ-II" to PROMCHOICE_ACT
Timing:	Baseline and annually
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Without Any Difficulty
	1 = With Some Difficulty
	2 = With Much Difficulty
	3 = Unable To Do

Variable ID:	HAQ2_Q04
Variable:	HAQ-II Question 4
Definition:	Are you able to:… Reach and get down a 5 pound object (such as a bag of sugar) from just above your head?
Supporting Definition:	N/A
Inclusion Criteria:	If "1 = HAQ-II" to PROMCHOICE_ACT
Timing:	Baseline and annually
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Without Any Difficulty

1 = With Some Difficulty
2 = With Much Difficulty
3 = Unable To Do

Variable ID:	HAQ2_Q05
Variable:	HAQ-II Question 5
Definition:	Are you able to:... Open car doors?
Supporting Definition:	N/A
Inclusion Criteria:	If "1 = HAQ-II" to PROMCHOICE_ACT
Timing:	Baseline and annually
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Without Any Difficulty
	1 = With Some Difficulty
	2 = With Much Difficulty
	3 = Unable To Do

Variable ID:	HAQ2_Q06
Variable:	HAQ-II Question 6
Definition:	Are you able to:... Do outside work (such as yard work)?
Supporting Definition:	N/A
Inclusion Criteria:	If "1 = HAQ-II" to PROMCHOICE_ACT
Timing:	Baseline and annually
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Without Any Difficulty
	1 = With Some Difficulty
	2 = With Much Difficulty
	3 = Unable To Do

Variable ID:	HAQ2_Q07
Variable:	HAQ-II Question 7
Definition:	Are you able to:... Wait in line for 15 minutes?
Supporting Definition:	N/A
Inclusion Criteria:	If "1 = HAQ-II" to PROMCHOICE_ACT
Timing:	Baseline and annually
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Without Any Difficulty
	1 = With Some Difficulty
	2 = With Much Difficulty
	3 = Unable To Do

Variable ID:	HAQ2_Q08
Variable:	HAQ-II Question 8
Definition:	Are you able to:... Lift heavy objects?
Supporting Definition:	N/A
Inclusion Criteria:	If "1 = HAQ-II" to PROMCHOICE_ACT
Timing:	Baseline and annually
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Without Any Difficulty
	1 = With Some Difficulty
	2 = With Much Difficulty
	3 = Unable To Do

Variable ID:	HAQ2_Q09
Variable:	HAQ-II Question 9
Definition:	Are you able to:... Move heavy objects?
Supporting Definition:	N/A
Inclusion Criteria:	If "1 = HAQ-II" to PROMCHOICE_ACT
Timing:	Baseline and annually

Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Without Any Difficulty
	1 = With Some Difficulty
	2 = With Much Difficulty
	3 = Unable To Do

Variable ID:	HAQ2_Q10
Variable:	HAQ-II Question 10
Definition:	Are you able to:... Go up two or more flights of stairs?
Supporting Definition:	N/A
Inclusion Criteria:	If "1 = HAQ-II" to PROMCHOICE_ACT
Timing:	Baseline and annually
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Without Any Difficulty
	1 = With Some Difficulty
	2 = With Much Difficulty
	3 = Unable To Do

Variable ID:	PROMCHOICE_OEPHI
Variable:	PROM Choice - Overall Emotional and Physical Health Impact
Definition:	Which Patient-Reported Outcome Measure are you using to measure overall emotional and physical health impact?
Supporting Definition:	Choose one from:
	Numerical Rating Scale (Patient Global Assessment)
	Visual Analogue Scale (Patient Global Assessment)
	PROMIS Global Health
	EQ-5D-5L
	SF-6D
	Raid
	Psaid
	PedsQL3.0
	PedsQL4.0
	PROMIS Global Health Paediatric
	EQ-5D-Y
Inclusion Criteria:	All patients
Timing:	Baseline and annually
Data Source:	Patient-reported
Type:	Single answer
Response Options:	1 = Numerical Rating Scale (Patient Global Assessment)
	2 = Visual Analogue Scale (Patient Global Assessment)
	3 = PROMIS Global Health
	4 = EQ-5D-5L
	5 = SF-6D
	6 = Raid
	7 = Psaid
	8 = PedsQL3.0
	9 = PedsQL4.0
	10 = PROMIS Global Health Paediatric
	11 = EQ-5D-Y

Variable ID:	OEPHI_NRS
Variable:	Overall Emotional and Physical Health Impact Numerical Rating Scale
Definition:	Circle the number that best describes how your arthritis has affected you overall during the last week.
Supporting Definition:	0 = No impact
	10 = Extreme impact
Inclusion Criteria:	If "1 = NRS (Patient Global Assessment)" to PROMCHOICE_OEPHI
Timing:	Baseline and annually

Data Source:	Patient-reported
Type:	Single answer
Response Options:	Numerical value between 0 and 10

Variable ID:	PROMCHOICE_WSHAP
Variable:	PROM Choice - Work/school/housework ability and productivity
Definition:	Which Patient-Reported Outcome Measure are you using to measure work/school/housework ability and productivity?
Supporting Definition:	Choose one from: WPAI PedsQL4.0 - School Function
Inclusion Criteria:	All patients
Timing:	Baseline and annually
Data Source:	Patient-reported
Type:	Single answer
Response Options:	1 = WPAI 2 = PedsQL4.0 - School Function

Variable ID:	WPAI_GH_Q01
Variable:	Work Productivity and Activity Impairment Questionnaire: General Health V2.0 (WPAI:GH) Question 1
Definition:	Are you currently employed (working for pay)?
Supporting Definition:	N/A
Inclusion Criteria:	If "1 = WPAI" to PROMCHOICE_WSHAP
Timing:	Baseline and annually
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = No 1 = Yes

Variable ID:	WPAI_GH_Q02
Variable:	Work Productivity and Activity Impairment Questionnaire: General Health V2.0 (WPAI:GH) Question 2
Definition:	The next questions are about the past seven days, not including today. During the past seven days, how many hours did you miss from work because of your health problems? Include hours you missed on sick days, times you went in late, left early, etc., because of your health problems. Do not include time you missed to participate in this study.
Supporting Definition:	N/A
Inclusion Criteria:	If "1 = Yes" to WPAI_GH_Q01
Timing:	Baseline and annually
Data Source:	Patient-reported
Type:	Numerical value
Response Options:	Numerical value

Variable ID:	WPAI_GH_Q03
Variable:	Work Productivity and Activity Impairment Questionnaire: General Health V2.0 (WPAI:GH) Question 3
Definition:	During the past seven days, how many hours did you miss from work because of any other reason, such as vacation, holidays, time off to participate in this study?
Supporting Definition:	N/A
Inclusion Criteria:	If "1 = Yes" to WPAI_GH_Q01
Timing:	Baseline and annually
Data Source:	Patient-reported
Type:	Numerical value
Response Options:	Numerical value

Variable ID:	WPAI_GH_Q04
Variable:	Work Productivity and Activity Impairment Questionnaire: General Health V2.0 (WPAI:GH) Question 4
Definition:	During the past seven days, how many hours did you actually work?
Supporting Definition:	N/A

Inclusion Criteria:	If "1 = Yes" to WPAI_GH_Q01
Timing:	Baseline and annually
Data Source:	Patient-reported
Type:	Numerical value
Response Options:	Numerical value

Variable ID:	WPAI_GH_Q05
Variable:	Work Productivity and Activity Impairment Questionnaire: General Health V2.0 (WPAI:GH) Question 5
Definition:	During the past seven days, how much did your health problems affect your productivity while you were working? Think about days you were limited in the amount or kind of work you could do, days you accomplished less than you would like, or days you could not do your work as carefully as usual. If health problems affected your work only a little, choose a low number. Choose a high number if health problems affected your work a great deal.
Supporting Definition:	Consider only how much health problems affected productivity while you were working Scale: 0 = Health problems had no effect on my work 10 = Health problems completely prevented me from working
Inclusion Criteria:	If ">0" to WPAI_GH_Q04
Timing:	Baseline and annually
Data Source:	Patient-reported
Type:	Numerical
Response Options:	Numerical value between 1 and 10

Variable ID:	WPAI_GH_Q06
Variable:	Work Productivity and Activity Impairment Questionnaire: General Health V2.0 (WPAI:GH) Question 6
Definition:	During the past seven days, how much did your health problems affect your ability to do your regular daily activities, other than work at a job? By regular activities, we mean the usual activities you do, such as work around the house, shopping, childcare, exercising, studying, etc. Think about times you were limited in the amount or kind of activities you could do and times you accomplished less than you would like. If health problems affected your activities only a little, choose a low number. Choose a high number if health problems affected your activities a great deal
Supporting Definition:	Consider only how much health problems affected your ability to do your regular daily activities, other than work at a job. Scale: 0 = Health problems had no effect on my daily activities 10 = Health problems completely prevented me from doing my daily activities
Inclusion Criteria:	If "1 = WPAI" to PROMCHOICE_WSHAP
Timing:	Baseline and annually
Data Source:	Patient-reported
Type:	Numerical
Response Options:	Numerical value between 1 and 10

Treatment-Specific Outcomes

Variable ID:	SAE
Variable:	Serious Adverse Events
Definition:	Has the patient suffered from any serious adverse events in the past 12 months?
Supporting Definition:	According to the FDA, a serious adverse event is an undesirable experience associated with the use of a medical product in a patient. The event is serious when the patient outcome is: death; life-threatening; hospitalisation; disability or

permanent damage; congenital anomaly/birth defect; required intervention to prevent permanent impairment or damage; other serious (important medical events).

Inclusion Criteria:	All patients
Timing:	Baseline and annually
Data Source:	Clinician
Type:	Single answer
Response Options:	0 = No
	1 = Yes
	999 = Unknown

Variable ID:	SAE_TYPE
Variable:	Serious Adverse Events - Classification
Definition:	Which serious adverse event(s) has the patient suffered from in the past 12 months?
Supporting Definition:	N/A
Inclusion Criteria:	If "1 = Yes" to SAE
Timing:	Baseline and annually
Data Source:	Clinician
Type:	Multiple answer
Response Options:	1 = Death
	2 = Life-threatening
	3 = Hospitalisation
	4 = Disability or permanent damage
	5 = Congenital anomaly/birth defect
	6 = Required intervention to prevent permanent impairment or damage
	7 = Other serious (important medical events)

Variable ID:	REM_LDA_TARG
Variable:	Disease activity target
Definition:	What was the disease activity target?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and annually
Data Source:	Clinician
Type:	Single answer
Response Options:	1 = Clinical remission
	2 = Low disease activity
	3 = Both
	999 = Unknown

Variable ID:	REM_LDA_REAC
Variable:	Disease activity target reached
Definition:	Was the disease activity target reached?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and annually
Data Source:	Clinician
Type:	Single answer
Response Options:	0 = No
	1 = Yes
	999 = Unknown

Variable ID:	IDA
Variable:	Inflammatory disease activity
Definition:	Which validated and internationally-accepted composite score for inflammatory disease activity did you use?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and 6-monthly if disease is active, baseline and annually if in remission
Data Source:	Clinician

Type:	Free text
Response Options:	Free text
Variable ID:	IDA_RES
Variable:	Inflammatory disease activity result
Definition:	What was the clinical composite score?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and 6-monthly if disease is active, baseline and annually if in remission
Data Source:	Clinician
Type:	Free text
Response Options:	Free text

Working Group Member Conflicts of Interest

At the beginning of the Working Group process, we ask all Working Group members to declare any conflicts of interest they have. We then circulate these within the Group to ensure transparency.

Name	Title	Declarations
Mart van de Laar	Professor of Rheumatology	Roche - research support
Harald Vonkeman	Associate Professor of Rheumatology	Roche - research support
Martijn Oude Voshaar	Senior Researcher	None declared
Zofia Das-Gupta	Project Leader	None declared
Angelique Weel	Associate Professor of Rheumatology	Abbvie - grant Pfizer - grant UCB - grant
Annelies Boonen	Professor of Rheumatology	
Benjamin Ellis	Consultant Rheumatologist Senior Clinical Advisor, Arthritis Research UK	Led on the development of the Musculoskeletal Health Questionnaire
Christina Opava	Professor of Physiotherapy	None delcared
Christine Hale	National Director of Clinical Performance Excellence	None declared
Delphine Courvoisier	Senior Researcher	BMS - personal fees
Enrique Soriano	Associate Professor of Rheumatology	Abbvie - grant, personal fees Brystol - grant, personal fees Pfizer - grant, personal fees Janssen - grant, personal fees UCB - grant, personal fees Roche - grant, personal fees Novartis - grant, personal fees
Geraldo Pinheiro	Associate Professor of Rheumatology	Abbvie - consulting honorarium AstraZeneca - consulting honorarium BMS - consulting honorarium Janssen - consulting honorarium Pfizer - consulting honorarium Roche - consulting honorarium Sanofi Aventis - consulting honorarium
Girish Mody	Professor of Rheumatology	GSK - honorarium (advisory board member - past) AstraZeneca - honorarium (advisory board member - past)
Jeffrey Chau	Patient Representative	Eli Lilly and Company - consulting fees Boehringer Ingelheim - consulting fees
Jeffrey Curtis	Professor of Medicine	Amgen - honorarium/research BMS - honorarium/research Corrona - honorarium/research Crescendo - honorarium/research Janssen - honorarium/research Pfizer - honorarium/research
Jennifer Horonjeff	Instructor Officer of Research	Boehringer-Ingelheim - honorarium
Johannes Bijlsma	Professor of Rheumatology	Abbvie - consulting fees BMS - consulting fees MSD - consulting fees Pfizer - consulting fees Roche - consulting fees SUN - consulting fees UCB - consulting fees
Kaleb Michaud	Associate Professor of Rheumatology	None declared
Katy Ying Ying Leung	Assistant Professor of Rheumatology	None declared

Laure Gossec	Professor of Rheumatology	Abbott - speaking fees/honorarium Abbvie - speaking fees/honorarium Celegne - speaking fees/honorarium Chugai - speaking fees/honorarium Janssen - speaking fees/honorarium MSD - speaking fees/honorarium Novartis - speaking fees/honorarium Pfizer - speaking fees/honorarium Roche - speaking fees/honorarium UCB - speaking fees/honorarium
Maarten de Wit	Patient Representative	Abbvie - committee fee Novartis - committee fee BMS - committee fee Celegne - speaking fee Roche - speaking fee
Marieke Voshaar	Patient Representative	None declared
Merav Lidar	Professor of Rheumatology	None declared
Mwidimi Ndosi	Senior Lecturer in Rheumatology	None declared
Nico Wulffraat	Professor of Paediatric Rheumatology	Abbvie - grant Novartis - speaking fees, drug trials Pfizer - grant Sanofi - grant
Philip Mease	Director of Rheumatology Research	Abbvie - research grant/consulting honorarium/speaking honorarium Amgen - research grant/consulting honorarium/speaking honorarium BMS - research grant/consulting honorarium/speaking honorarium Janssen - research grant/consulting honorarium/speaking honorarium Novartis - research grant/consulting honorarium/speaking honorarium Pfizer - research grant/consulting honorarium/speaking honorarium UCB - research grant/consulting honorarium/speaking honorarium Celegne - speaking honorarium Genentech - speaking honorarium Crescendo Bioscience - consulting/speaking honorarium Galapagos - consulting honorarium Lilly - consulting honorarium SUN - consulting honorarium Corrona - consulting honorarium
Sofia Ernestam	Rheumatology Specialist	None declared
William Taylor	Associate Professor of Rheumatology	None declared

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Reference Guide Revisions

Reference Guide Version	Location within Reference Guide	Content Change

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