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2018 EULAR recommendations for a core data set to support observational research and clinical care in giant cell arteritis

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Abstract

Background:

Giant cell arteritis (GCA) represents the most common form of primary systemic vasculitis, and is frequently associated with comorbidities related to the disease itself or induced by the treatment. Systematically collected data on disease course, treatment and outcomes of GCA remain scarce.

Objectives:

The aim of this EULAR Task Force was to identify a core set of items which can easily be collected by experienced clinicians, in order to facilitate collaborative research into the course and outcomes of GCA.

Methods:

A multidisciplinary EULAR task force group of 20 experts including rheumatologists, internists, epidemiologists and patient representatives was assembled. During a one-day meeting, breakout groups discussed items from a previously compiled collection of parameters describing GCA status and disease course. Feedback from breakout groups was further discussed. Final consensus was achieved by means of several rounds of email discussions after the meeting. A three-round Delphi survey was conducted to determine a core set of parameters including the level of agreement.

Results:

117 parameters were regarded as relevant. Potential items were subdivided into the following categories: General, demographics, GCA-related signs and symptoms, other medical conditions, and treatment. Possible instruments and assessment intervals were proposed for documentation of each item. To facilitate implementation of the recommendations in clinical care and clinical research, a minimum core set of 50 parameters was agreed.

Conclusion: This proposed core set intends to ensure that relevant items from different GCA registries and databases can be compared for the dual purposes of facilitating clinical research and improving clinical care.

Introduction

Giant cell arteritis (GCA) is the most common primary systemic vasculitis in western countries with a lifetime risk of 1.0% for women and 0.5% for men over the age of 50 years.(1, 2) Now considered to have cranial and large vessel manifestations, its clinical features include new headache, scalp tenderness, temporal artery abnormality (such as thickening, tenderness, and/or pulselessness) and systemic manifestations such as polymyalgic symptoms, weight loss, fatigue and fever.(1-3) Sight loss has become less common in recent years,(4) but is still reported in 14-18% of GCA patients,(5) supporting the urgency of diagnosis and treatment. Rarer ischaemic complications of GCA include stroke, cranial nerve palsy and scalp necrosis. GCA may also be complicated by large-vessel aneurysms and vascular stenoses.

Erythrocyte sedimentation rate and/or C-reactive protein are the traditionally used markers to assess disease activity. These markers are elevated in >95% of GCA cases at diagnosis. Temporal artery biopsy with specimen length of ≥1cm performed by an experienced surgeon and evaluated by an experienced pathologist revealing histopathological features of temporal arteritis is an established procedure for diagnosis of cranial GCA. Imaging techniques such as vascular ultrasound (US), magnetic resonance imaging (MRI), ^{18}F-FDG-positron emission tomography (PET), and contrast-enhanced computed tomography (CT) are increasingly used for diagnosis of GCA, and for identifying disease extent. A clinically suspected diagnosis of GCA should be confirmed either histologically or by imaging (e.g. ‘halo’ and ‘compression’ sign on ultrasound).(6) Histopathological hallmarks of GCA include arterial wall thickening, narrowed lumen, presence of mononuclear inflammatory cells with media invasion and rarely necrosis, and multinucleated giant cells in the media.(7) Characteristic imaging findings in GCA include inflammatory wall swelling of cranial and extracranial arteries (described as ‘halo’ sign on ultrasound or circumferential wall thickening on CT scan), often with increased tracer uptake in the arterial wall in case contrast media (CR, MRI) or radionuclides (PET) have been used. The recently published EULAR recommendations provide details on the application of these techniques in large vessel vasculitis in clinical practice.(8)

GCA has been treated almost exclusively with glucocorticoid (GC) monotherapy for decades. Flare (relapse) occurs in 34-62% of patients, and only 15-20% of patients achieve sustained remission with GCs alone.(9) A modest reduction of the cumulative GC dose may be achieved by adjunctive methotrexate; the value of other conventional

disease modifying antirheumatic drugs remains unclear.(1) Tocilizumab (TCZ) has demonstrated efficacy in reducing GC requirements and flare rates in patients with GCA followed for up to 52 weeks,(10, 11) and has been recently approved by the Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for GCA, and by the National Institute for Health and Care Excellence (NICE) for refractory and relapsing disease. Other novel therapeutic approaches either recently or currently investigated include inhibition of IL-1beta (e.g. canakinumab), blockade of T cell co-stimulation (e.g. abatacept), and blocking Janus kinases (JAK) 1/2 (e.g. baricitinib: NCT03026504).(9, 12)

There are many unanswered questions with regard to identification and prognosis of various GCA subgroups, monitoring disease outcomes and co-morbidities, treatment course, and seeking cost-effective treatment strategies in GCA. Registry infrastructures are necessary to address the lack of robust real-world data on sight loss, vascular and other disease-related complications and specific co-morbidities such as diabetes or osteoporosis, as well as adverse events induced by GC and other treatments. The advent of novel diagnostic modalities and therapies, and improved recognition of the short- and long-term disease- and treatment-related complications, emphasise the pressing need to establish national and multinational GCA registries and databases for systematically collecting data on demographics, diagnostic strategies, and utility and safety of therapeutic approaches.

The number and comprehensiveness of prospective cohort studies including patients with GCA lag behind what is available for other rheumatic and musculoskeletal diseases. The utility of registry data to inform clinical practice, policy decisions and translational research has been demonstrated, for example in registries of rheumatoid arthritis (RA).(13, 14) Large collaborative projects from several European biologic registries provided reassuring results regarding risk of melanoma (13) and distribution of lymphoma subtypes (14) in patients with RA following exposure to TNF inhibitors.

With this as background, the task force aimed to develop a minimum core set of parameters collected for newly and previously diagnosed patients with GCA to ensure that data from different registries and databases are standardised in order to facilitate collaborative analyses. Analyses of information resulting from merging or linking of individual registries or databases, each of which have collected these core parameters, could enable identification of as yet unknown prognostic factors for favourable and

unfavourable disease progression as well as treatment-associated comorbidities, and inform a benefit-risk assessment of available therapies for GCA.

Methods

The Task Force membership from 10 countries comprised 16 rheumatologists (including one Emerging EULAR Network (EMEUNET) member), internal medicine specialists and epidemiologists, 2 patient representatives, 1 representative from the European Medicines Agencies' Cross-Committee Task Force on Registries, and 1 rheumatology fellow.

Prior to the work group meeting, all participants were asked to suggest items including appropriate instruments and measurement intervals they considered indispensable for the creation of a GCA registry or database **(Figure 1)**. The initial collection was completed by items identified by a non-systematic literature review in PubMed performed by the fellow. Search terms included "vasculitis", "giant cell arteritis", "polymyalgia rheumatica" accompanied by "outcome measures", "registry", "core data set", "reporting", and "epidemiology". Potentially relevant domains and items were identified by scanning related work done in polymyalgia rheumatica (PMR) (15-18) and RA.(19, 20) The compilation of items was also counterchecked with current guidelines on the management of GCA (1, 21) as well as EULAR, European Vasculitis Society (EUVAS) and European Union Committee of Experts on Rare Diseases (EUCERD) recommendations on data collection and patient registries.(22-26) Review of parameters collected in pertinent representative epidemiological studies served as an internal control to verify relevance of the selected items.(27-29) Both the feedback from the participants and the results of the literature review served as guidance for the subsequent group discussions.

Step 1 consisted of a one-day face-to-face meeting, during which the Task Force members were assigned to three breakout groups focussing on different categories of items: demographics and disease phenotype, treatment and response, and safety outcomes. Individual group discussions then ranked the identified items and assigned them to three different categories: items that represent an essential part of a GCA registry or database, questionable items, and items that should not be part of the core set of parameters. Items were also assessed for their importance for clinical care and research purposes. The results were presented to the whole group with subsequent discussion by all participants.

After the meeting, all groups were asked to (i) re-evaluate their assembled data items for monitoring disease treatment and outcomes, (ii) determine the required corresponding instruments, and (iii) suggest the frequencies at which these data items should be collected or measured. In subsequent mailing rounds, strategies for dealing with additional items were discussed. As a result, a minimum core set of parameters was generated. The final methodological steps comprised concluding discussions, harmonisation of feedback, consensus finding, and anonymous voting on the level of agreement. In order to achieve final consensus, we first defined exactly the scope specification, stakeholder involvement, and the steps of this process.(30) As a result, we initiated a three-round Delphi survey: Starting with a list of items resulting from preceding rounds of discussion all 20 participants of the task force were at first asked to evaluate each parameter with regard to the following question, “Should this item be part of a minimum core set of parameters for the creation of a GCA registry or database?”, allowing only “yes” or “no” as an answer. Consensus for inclusion was met when at least 70% voted in favour of the respective item. In contrast, all parameters reaching less than 50% of the votes were excluded from the set. According to the comments of the task force, the items having achieved between 50 and 69% in the first round were modified and, in the second Delphi round, the task force members were asked to reconsider these items. Consensus for an item to be included in the next voting step was defined as at least 70% agreement. All items having met this consensus were then considered in the third voting step to form a level of agreement, whereas items not reaching this level of agreement were excluded. Every participant was asked to rate every parameter on a scale of 0 (no agreement) to 10 (absolute agreement). Only items achieving a mean level of agreement of at least 7 in the 3rd Delphi round were included in the final core set of parameters for the creation of a GCA registry or database. It should be noted that the proposed suitable instruments and assessment intervals for each item were not subjected to the voting process. They were included during the voting process to aid understanding of the taskforce participants, and are included in **Table 1** to illustrate possible ways of measuring the agreed items.

Results

Initially, the task force members gathered 51 items describing demographics and disease phenotype, 38 items related to treatment and response, and 30 items to

assess safety outcomes. This first set was completed by identification of missing items by reviewing the literature, resulting in addition of 6 further items required for calculation of the Charlson Comorbidity Index.(31) Existing work on data collection in PMR and RA (15-20) revealed another 6 parameters, namely ethnicity, fatigue, functional capacity, quality of life, morning stiffness, and cumulative GC dose. No instruments relating to GCA were found in the EULAR Outcome Measures Library.(32) The task force ensured that applicable parameters from the Vasculitis Damage Index were included (33) and that the set was consistent with current guidelines on the management of GCA and PMR.(1, 21) Also, this step served to ensure that the collection met the EULAR "points to consider for reporting, screening for and preventing selected comorbidities in chronic inflammatory rheumatic diseases in daily practice."(22) Additionally, EULAR, EUVAS and EUCERD recommendations (22-26) provided guidance for necessary data points in creating the original list of items to ensure harmonised data exchange. Items were adjusted accordingly. Discussion and modification of this initial data set at a one-day task force meeting resulted in a compilation of 117 items (**Figure 2**, outer circle) regarded as possibly relevant. The original domains were also reconsidered in order to reduce redundancy and facilitate data collection, resulting in the following adjusted categories: General, demographics, GCA-related signs and symptoms, other medical conditions, and treatment. By means of several rounds of email discussions after the meeting, the number of items was reduced to 98 items (**Figure 2**, middle circle) considered important, but not obligatory, for the creation of a GCA registry. The final consensus was to provide a minimum core set of parameters in order to facilitate implementation of the recommendations in both clinical care and clinical research. Sixty-six items (**Figure 2**, inner circle) were considered suitable for evaluation in a final three-round Delphi survey. The first round identified 50 items meeting the consensus of 70% agreement to be eligible for the final level of agreement, 14 items to be re-evaluated in the second round, and 2 items to be excluded. During the second round, 5 of the 14 reconsidered items met the consensus of 70% of the votes whereas 9 parameters were definitely excluded from the core set. Prior to the next voting round and in accordance with the predominant feedback, the selection of 55 items eligible for the final level of agreement was reduced to 50 by merging 5 items describing cranial artery abnormalities into one item, and by combining the parameters dilatation and aneurysm of the aorta. Finally, all the remaining 50 items achieved a level of agreement of at least 7 in the third voting step

and were thus ultimately selected for the final minimum core set of parameters. Our final result, i.e. the 50 items within the 5 suggested categories, and proposed instruments and assessment intervals, is provided in **Table 1**. This core data set should be recorded in patients with a clinical diagnosis of GCA made by an expert in the disease, ideally supported by characteristic imaging and histological findings.(8) This will facilitate subsequent evaluation of the items used by clinicians in making a diagnosis of GCA.

Table 1: Minimum core set of parameters to be collected in giant cell arteritis registries and databases

Item	Instrument	Baseline	Follow-up	LoA[#]
General				
patient identifier		x	x	9,85 ± 0,49 [8;10] (100%)
visit date	date	x	x	9,90 ± 0,31 [9;10] (100%)
Demographics				
age*	date of birth	x		9,95 ± 0,23 [9;10] (95%)
sex	male/female	x		9,95 ± 0,22 [9;10] (100%)
weight	kg (measure)	x	x	8,65 ± 1,42 [5;10] (95%)
height	cm (measure)	x	x	8,50 ± 1,36 [5;10] (95%)
smoking	never/past/current, pack-years	x	x	9,25 ± 0,91 [8;10] (100%)
GCA diagnosis	ICD-10 code (M31.5 / M31.6)	x		9,60 ± 0,75 [8;10] (100%)
date of GCA diagnosis	date (medically reported diagnosis)	x		9,60 ± 0,82 [8;10] (100%)
onset of symptoms	date (interview)	x		8,95 ± 1,73 [3;10] (95%)
GCA-related signs & symptoms				
cranial				
ocular involvement				
ocular symptoms: diplopia, blurring, transient visual loss (amaurosis fugax)	interview	x	x	9,25 ± 1,48 [4;10] (95%)
permanent partial visual loss / field defect / blindness / RAPD*	examination	x	x	9,20 ± 1,36 [5;10] (95%)
*headache**	interview	x	x	9,05 ± 1,88 [2;10] (95%)
*scalp tenderness**	interview	x	x	8,45 ± 2,14 [1;10] (90%)
jaw claudication	interview	x	x	8,40 ± 2,21 [1;10] (90%)
cranial artery abnormality				
cord-like thickening / nodularity / tenderness / reduced pulse and/or pulselessness	examination	x	x	8,35 ± 2,56 [0;10] (85%)
sonographic evidence of arteritis*	ultrasound	x	x	8,30 ± 2,64 [0;10] (80%)
histological arteritis*	biopsy	x		8,84 ± 2,54 [0;10] (85%)
constitutional: fever/pyrexia symptoms*	interview	x	x	8,10 ± 2,20 [3;10] (75%)
laboratory				
ESR	mm/h (1^{st} h)	x	x	9,10 ± 1,29 [6;10] (95%)

CRP	e.g. in mg/dL	x	x	9,55 ± 0,94 [7;10] (100%)
haemoglobin	e.g. in g/dL	x	x	7,50 ± 2,59 [0;10] (75%)
PMR*	interview, examination	x	x	9,45 ± 0,94 [7;10] (100%)
large vessel involvement				
*peripheral pulses**	examination	x	x	8,10 ± 2,34 [2;10] (70%)
blood pressure	mmHg (left & right arm)	x	x	7,90 ± 2,15 [1;10] (80%)
*dilatation/aneurysm**	US / MR / CT	x	x	7,79 ± 3,05 [0;10] (75%)
*inflammatory wall thickening**	US / MR / CT	x	x	7,15 ± 3,17 [0;10] (65%)
*stenosis**	US / MR / CT	x	x	7,50 ± 3,00 [0;10] (75%)
disease activity				
*patient's global assessment of disease activity**	NRS	x	x	8,70 ± 2,27 [1;10] (90%)
*evaluator's global assessment of disease activity**	NRS	x	x	8,55 ± 2,50 [0;10] (85%)
Other medical events or conditions				
death	date, cause		x	9,70 ± 0,73 [8;10] (100%)
cardiovascular				
*TIA**	date	x	x	8,70 ± 1,84 [3;10] (90%)
*stroke**				
ischaemic	date	x	x	8,84 ± 2,14 [2;10] (85%)
haemorrhagic	date	x	x	8,10 ± 2,25 [1;10] (85%)
myocardial infarction	date	x	x	8,42 ± 2,12 [1;10] (90%)
*arterial hypertension**	interview, medical report	x	x	8,45 ± 2,35 [0;10] (90%)
endocrine				
*diabetes mellitus**	interview, medical report	x	x	8,70 ± 1,69 [4;10] (90%)
*osteoporosis**	interview, medical report, BMD	x	x	8,60 ± 1,43 [5;10] (90%)
infection				
active tuberculosis	date	x	x	8,00 ± 2,03 [4;10] (75%)
*serious infection**	date, type	x	x	9,00 ± 1,12 [7;10] (100%)
malignancy				
haematopoietic	date, type	x	x	9,05 ± 1,05 [7;10] (100%)
solid tumour	date, type	x	x	9,05 ± 1,05 [7;10] (100%)
skin	date, type	x	x	7,95 ± 1,85 [4;10] (85%)
other serious event*	date, specify	x	x	8,15 ± 2,01 [3;10] (75%)

Treatment				
glucocorticoids				
*current use**	dose	x	x	9,80 ± 0,52 [8;10] (100%)
*recent use**	interview, medical report	x	x	9,75 ± 0,55 [8;10] (100%)
immunosuppressants/-modulators*				
conventional synthetic DMARDs	current medication	x	x	9,75 ± 0,55 [8;10] (100%)
	historical treatment	x		
biological DMARDs	current medication	x	x	9,90 ± 0,31 [9;10] (100%)
	historical treatment	x		
targeted synthetic DMARDs	current medication	x	x	9,80 ± 0,41 [9;10] (100%)
	historical treatment	x		
antiplatelet agents*	current medication	x	x	9,15 ± 0,93 [7;10] (100%)
	historical APT	x		

[#] Level of agreement (LoA) was based on an anonymized survey with a 0-10 scale by all members of the task force (data are mean ± standard deviation [minimum; maximum rating] and in brackets the percentage of task force members with an agreement ≥ 7))
* See online supplementary text for a more detailed item description and information on collection instruments and intervals.
AE, adverse event; APT, antiplatelet therapy; BMD, bone mineral density; CRP, C-reactive protein; CT, computed tomography scan; DMARD, disease-modifying anti-rheumatic drug; ESR, erythrocyte sedimentation rate; GC, glucocorticoid; GCA, giant cell arteritis; HCP, health care professional; LoA, level of agreement; MR, magnetic resonance imaging; NRS, numeric rating scale; PMR, polymyalgia rheumatica; RAPD, relative afferent pupillary defect; TIA, transient ischaemic attack; US, ultrasound.

Discussion

The aim of this task force was to identify a EULAR endorsed core set of parameters to facilitate the uniform collection of data on the disease characteristics and the course of GCA in newly and previously diagnosed patients. This core set aims for harmonization of the collection process with the aim of enhancing the comparability of clinical care data across national and multinational GCA registries and databases and of facilitating pooled analyses to address clinical research questions. This standardized and systematic collection of relevant data opens new avenues for collaboration between researchers to improve clinical care.

The development of this minimum core set of parameters was informed by the trade-off between what is scientifically desirable and what is clinically feasible in routine rheumatology clinical practice. The core set is the result of a rigorous and intentional selection and prioritization process, during which parameters that may have importance for some applications were dropped from consideration **(Figure 2)**.

Very recently, a EULAR task force has published an RA core set of 21 items (’what to collect’) and their instruments (’how to collect’) in order to facilitate standardised RA data collection in clinical practice and research.(19) The authors stress the term ‘core’ to underscore that the set represents a minimum number of items, acknowledging that individual stakeholders are likely to add items or instruments. Our approach was purposely somewhat different than that taken by the EULAR RA task force. Here, the primary aim was to provide a minimum but nevertheless ‘full’ or ‘complete’ core set, thereby reducing the likelihood that items or instruments would need to be added at a later date. Compared with the RA core set, the GCA core set is a larger ‘stand-alone set’ of items. This more comprehensive dataset can be collected in clinical practice, since documentation of many of the suggested parameters is necessary for routine clinical care. At the same time, this comprehensive minimum core set of items is not only scientifically desirable but is necessary to address unanswered questions in diagnosis and treatment of GCA. Those questions include but are not limited to the following:

1. What are the most effective instruments to diagnose and monitor GCA?
2. How high is the burden of GC-related morbidity, particularly in elderly patients affected by GCA?

3. What are effective treatments of refractory patients who are not responsive or only partial-responders to GCs, or patients in whom GCs are contra-indicated or associated with major adverse effects?
4. What is the outcome and prognosis in subgroups of patients with GCA, such as those accruing aortic or other large vessel damage despite apparent response to GCs, with or without conventional immunosuppressants?

These examples of current questions illustrate that systematically collecting parameters in national and multinational registries for cohort studies is urgently needed. The recommended dataset of 50 items in 5 categories is likely to provide scientifically sound answers but can still be collected in routine clinical practice. The details given in **Table 1** and in the online supplementary text reflect that the list for GCA is not only larger than the one for RA for reasons outlined above, it additionally includes suggested intervals (although not subjected to the voting process) when these parameters should be collected.

A potential weakness of the proposed data set is uncertainty about whether it represents the optimal compromise between what is scientifically desirable and what is clinically feasible in routine clinical practice. If the set of parameters is too small, the scientific quality of data may be limited. The task force had long and intensive discussions about what items ultimately should be integrated into the final minimum core set. Members were cognisant that the practical usage of such a dataset may be seriously compromised if the parameter list is too long and complex. That is why items such as peripheral arthritis, scalp necrosis, tongue claudication; health-related quality of life, cushingoid aspect, cataract and depression were not included **(Figure 2)**. The task force considers most of these parameters including patient-reported outcomes as fundamental and supports the addition of items to the core set whenever feasible and informative. The members were also reluctant to include generic items capturing health-related quality of life since there are to date no GCA-specific tools. Further research is needed to develop PROs, particularly assessing quality of life, burden of disease and social impact of GCA. The task force is aware of the effort that the collection of a comprehensive data set imposes on clinical staff. In order to facilitate collection, the members therefore included binary items that can be evaluated by a directed interview and clinical examination. Also, it must be pointed out that several disease features captured as items, however common they may be in GCA, are often

subtle or subjective (e.g. cranial artery abnormalities). That is why clinicians need to be well-trained in order to evaluate these symptoms and collect reliable data.

The level of adoption of these recommendations will reveal whether trade-off decisions were appropriate and whether revisions in one or the other direction will be needed in the future. Nevertheless, the consensus represented by this initiative is an important step towards increasing the quality of GCA data collection in both clinical practice and research.

Finally, while the Task Force has intentionally not discussed principles of governance and financing of registries in this paper, these issues must be addressed in order for registries to be sustainable and to guarantee their independence, transparency and scientific standards. This is of particular importance if registry data are to be used in support of regulatory or health technology assessment decision-making, or by corporations in fulfilling regulatory requirements.

Figure legends

Figure 1: Schematic representation of the consensus process for a core set of data to be collected in giant cell arteritis registries and databases

Figure 2: Parameters considered for a core set of data items to be collected for newly and previously diagnosed patients with GCA in registries and databases

Legend:

Outer circle: original selection of items considered relevant after the first task force meeting

Middle circle: reduced selection of items considered important, but not obligatory, for the creation of a GCA registry after several rounds of email discussions

Inner circle: minimum core set of items eligible for the final three-round Delphi survey

ACE, angiotensin converting enzyme; ARB, angiotensin II receptor blocker; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; DVT, deep venous thrombosis; GCA, giant cell arteritis; HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus; ILD, interstitial lung disease; ROM, range

of motion; PAD, peripheral artery disease; PET, positron-emission tomography; PPI, proton-pump inhibitor; VZV, varicella zoster virus

Contributors

We declare that all authors included on this paper fulfil the criteria of authorship.

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Competing interests

Lisa Ehlers has no conflicts of interest to declare.

Johan Askling has or has had research agreements with Abbvie, BMS, MSD, Pfizer, Roche, Astra-Zeneca, Eli Lilly, Samsung Bioepis, and UCB, mainly in the context of safety monitoring of biologics via ARTIS. Karolinska Institutet has received remuneration for JA participating in advisory boards arranged by Pfizer and Eli Lilly.

Johannes W.J. Bijlsma reported serving as coordinating investigator (Roche and SUN) in GCA and GC trials, and consultant and speaker for Roche.

Maria C. Cid reported receiving consultation/lecturing fees from Roche, GSK, Novartis, Boehringer-Ingelheim, Vifor and Abbvie and research funding from Kiniksa.

Maurizio Cutolo reported serving as coordinating investigator (Mundipharma, Horizon) and consultant (Mundipharma, Horizon) in PMR trials.

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Kate Gilbert has received consultancy fees from PMRGCAuk re facilitation of patient engagement with medical research in PMR and GCA.

Sarah Mackie has been an investigator for GCA trials (Roche, GSK), has had medical advisory group consultancies (Roche, Sanofi, Chugai), and is a Patron of the charities PMRGCAuk and PMR and GCA North East.

Alfred Mahr reported receiving consultancy fees and honoraria from Roche-Chugai.

Eric Matteson reported serving as coordinating investigator (Novartis) and consultant (Glaxo-Smith-Kline) in PMR trials, consultant (Glaxo-Smith-Kline, Endocyte) and as site investigator in GCA trials (Bristol Meyer Squibb, Hoffman-La Roche, Genentech, Glaxo-Smith-Kline), and editor, contributor for PMR/GCA (UpToDate, Paradigm).

Lorna Neill has no conflicts of interest to declare but reports to serve as Chair of PMR-GCA Scotland with no financial reward involved.

Carlo Salvarani reported serving as coordinating investigator (Roche) and consultant (Roche) in GCA trials.

Wolfgang A. Schmidt reported receiving consultancy fees, honoraria and a grant support from Roche, consultancy fees and honoraria from GlaxoSmithKline and consultancy fees from Sanofi. He was principle investigator in a GCA trial (GlaxoSmithKline).

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Ronald van Vollenhoven reported receiving research support and grants from AbbVie, BMS, GSK, Pfizer, and UCB. He served as consultant for AbbVie, AstraZeneca, Biotest, BMS, Celgene, Crescendo, GSK, Janssen, Lilly, Merck, Novartis, Pfizer, Roche, and UCB.

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