



Core Outcome Measures in Effectiveness Trials

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Core outcome set for trials

- An agreed standardised set of outcomes that should be measured and reported, as a minimum, in all clinical trials in specific areas of health or health care

REVIEW

Open Access

The COMET Handbook: version 1.0



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GUIDELINES AND GUIDANCE

Core Outcome Set-STANDards for Development: The COS-STAD recommendations

Jamie J. Kirkham¹, Katherine Davis¹, Douglas G. Altman², J Sean Tunis⁵, Paula R. Williamson^{1*}

Prinsen et al. *Trials* (2016) 17:449
DOI 10.1186/s13063-016-1555-2

Trials

RESEARCH

Open Access

How to select outcome measurement instruments for outcomes included in a “Core Outcome Set” – a practical guideline



Cecilia A. C. Prinsen^{1*}, Sunita Vohra^{2,3,4}, Michael R. Rose⁵, Maarten Boers^{1,6}, Peter Tugwell⁷, Mike Clarke⁸, Paula R. Williamson⁹ and Caroline B. Terwee¹

Harman et al. *Trials* 2013, 14:70
<http://www.trialsjournal.com/content/14/1/70>

Abstract

Background: In cooperation with the Core Outcome Set-STANDards for Development (COS-STAD) group, we developed a guideline on how to select outcome measurement instruments for outcomes included in a “Core Outcome Set” (COS). The guideline was developed and reported in all clinical trials of a

Methods: Informed by a literature review to identify outcome measurement instruments, a Delphi study was performed with 120 invited experts and 120 stakeholders. In three consecutive rounds, panels of outcome measurement instruments, to justify their selection, were presented to the panels as being achieved when 70 % or more of the panel agreed.

Results: Of the 481 invited experts, 120 agreed to participate in the study. We reached consensus on four instruments for COS: Step 1, conceptual considerations; Step 2, a systematic review and/or a literature search; Step 3, means of the evaluation of the measurement instrument; and Step 4, generic recommendations on the selection of a COS (consensus ranged from 70 to 99 %).

Conclusions: This study resulted in a consensus-based guideline for the selection of outcome measurement instruments for outcomes included in a COS. The

STUDY PROTOCOL

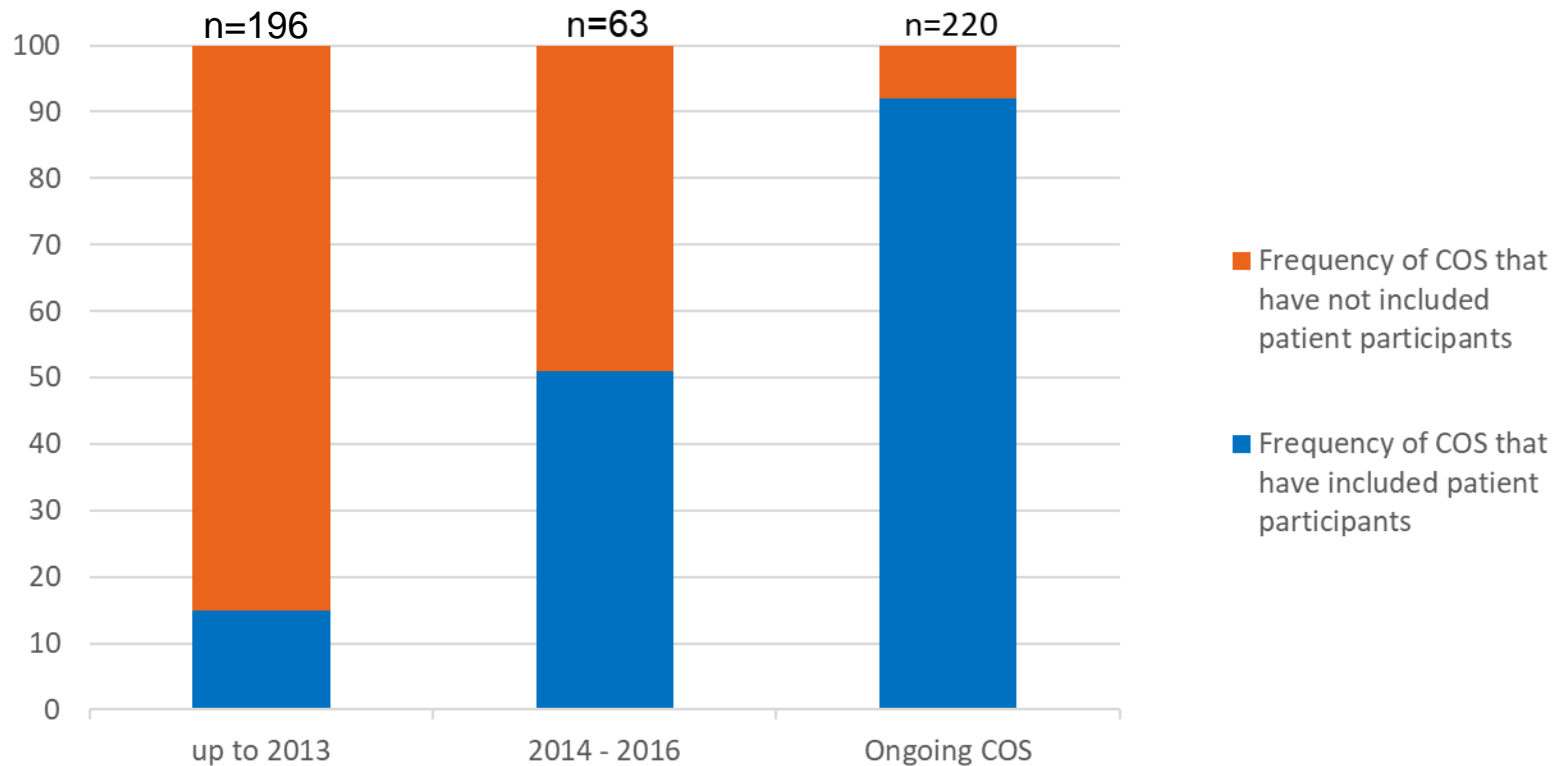
Open Access

MOMENT – Management of Otitis Media with Effusion in Cleft Palate: protocol for a systematic review of the literature and identification of a core outcome set using a Delphi survey

Nicola L. Harman¹, Iain A. Bruce², Peter Callery³, Stephanie Tierney³, Mohammad Owaise Sharif¹,

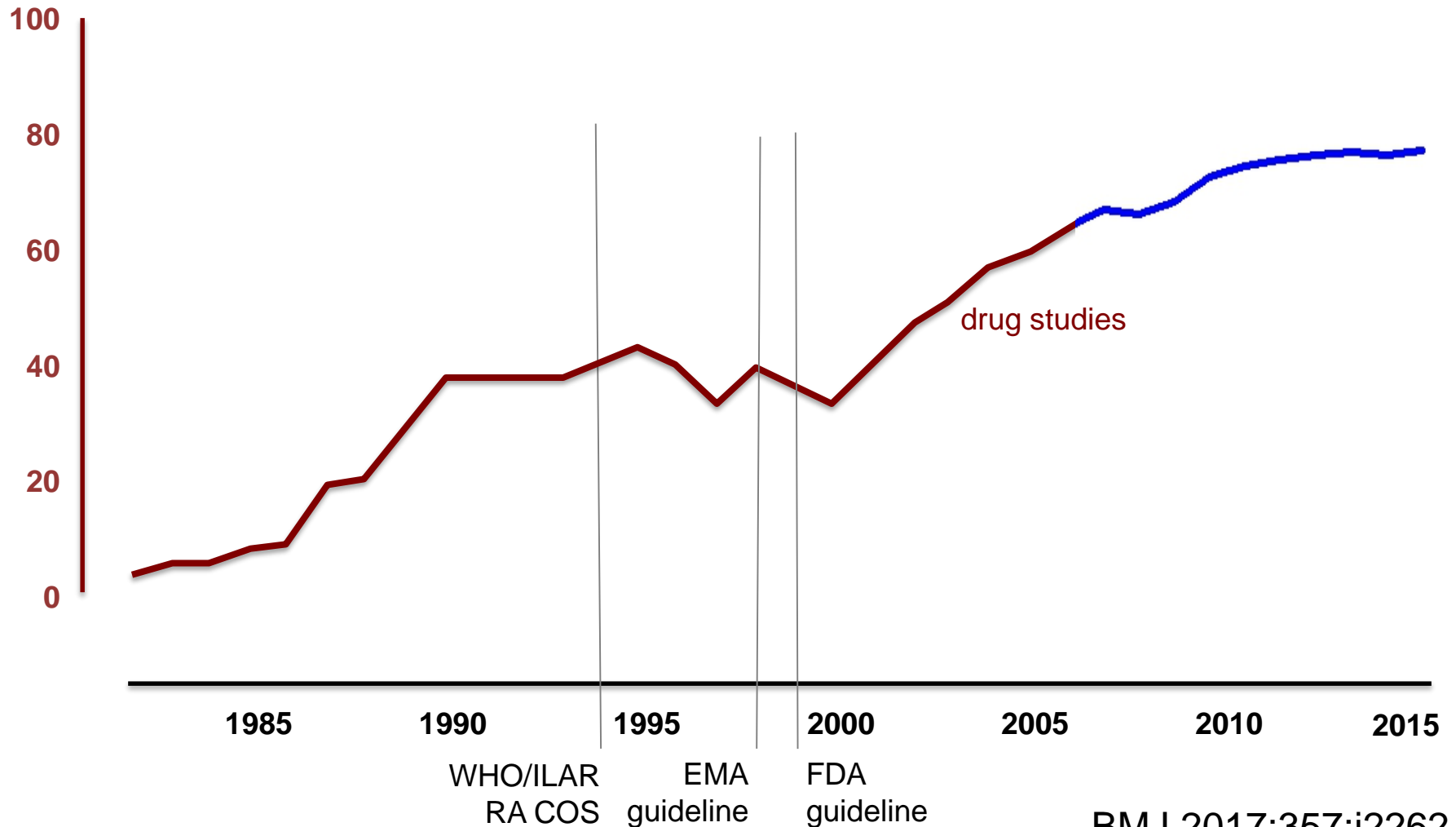


“Doctors know about the illness, but patients know about the impact”



Improvements over time (Kirkham et al, *BMJ* 2017)

Studies measuring
full RA COS (%)



Examining trial reports to assess uptake

- ▶ **Ankylosing spondylitis (2009)** - 20% uptake of full COS (>2 years after COS publication) compared to 0% uptake of full COS (up to 2 years after)
- ▶ **Chronic pain (2008)** - looked at uptake of individual outcomes in the COS – each of the COS outcomes were used in 99%, 94%, <50%, <50%, <50%, <50%, <50%, <50%, 7%
- ▶ **Gout (2005)** - 5% uptake of full COS (acute), 0% uptake of full COS (chronic)
- ▶ **Fall injury prevention (2005)** - 3% uptake of full COS
- ▶ **Knee arthroplasty (1997)** - 4% uptake of full COS

COS Uptake and Endorsement

It is important to assess the uptake and use of COS in clinical trials, and other research, in order to avoid the development of these COS contributing to the research waste which their development aims to reduce. Assessing uptake can also highlight the benefits of measuring and reporting COS in trials while allowing review and feedback to ensure ongoing relevance, and removal of barriers and facilitators to uptake.

The following organisations actively endorse the use of COS and the COMET database.

Trialists

- ▄ SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials

Trial Funders

- ▄ National Institute for Health Research (NIHR), UK:Guidance Notes For Completing Full Proposals
- ▄ Horizon2020:
 - ▄ <http://ec.europa.eu/research/participants/portal/desktop/en/opportunities/h2020/topics/sc1-pm-10-2017.html>
- ▄ Deutsche Forschungsgemeinschaft (DFG) German Research Foundation
- ▄ Proposal Preparation Instructions: Clinical Trials Programme – Draft Proposals
- ▄ Proposal Preparation Instructions: Clinical Trials Programme – Full Proposals
- ▄ Arthritis Research UK (ARUK)
- ▄ Health Research Board (HRB)

Trial Registries

- ▄ ISRCTN

Regulatory Authorities



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- ▄ COMET blogs

Outcomes – from the very start



Clinical trials are only as credible as their outcomes

Tugwell, 1993



Equally true for systematic reviews as well



...and clinical guidelines

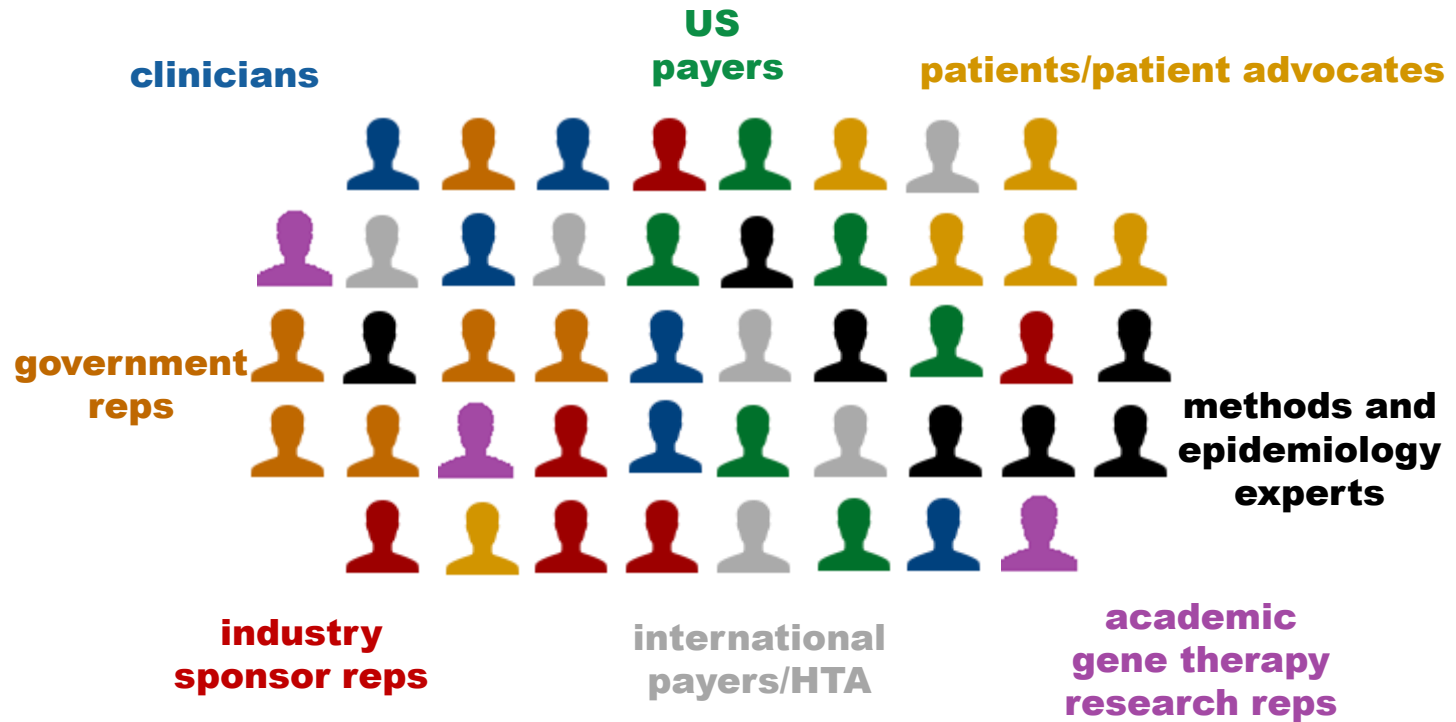


...and healthcare organisations

NICE: Hip fracture guideline 2017

- Submitted comment: *“The protocol in both update questions does not include reference to the published Core Outcome Set for hip fracture which is the best guide we have for appropriate outcomes and measurement instruments for use in this population. <http://www.comet-initiative.org/studies/details/274>”*
- Developers’ response: *“Thank you for your comment. The committee agreed that it was important to consider the Core Outcome Set (COS) for hip fracture in their deliberations on outcomes to consider (section 2.4 evidence to recommendations).....”*

coreHEM Stakeholders



SCORE-IT

1 2 3 4 5 6 7 8 9

International patient organisations approached with an invite to participate

International health professional association groups approached with an invite to participate

two round online Delphi

Currently translated into Brazilian Portuguese Polish German

researchers approached via professional organisations plus known grant holders

International HTA organisations identified and invited to participate - one person per organisation

Key Stakeholder Groups

People with type 2 diabetes

Healthcare Professionals

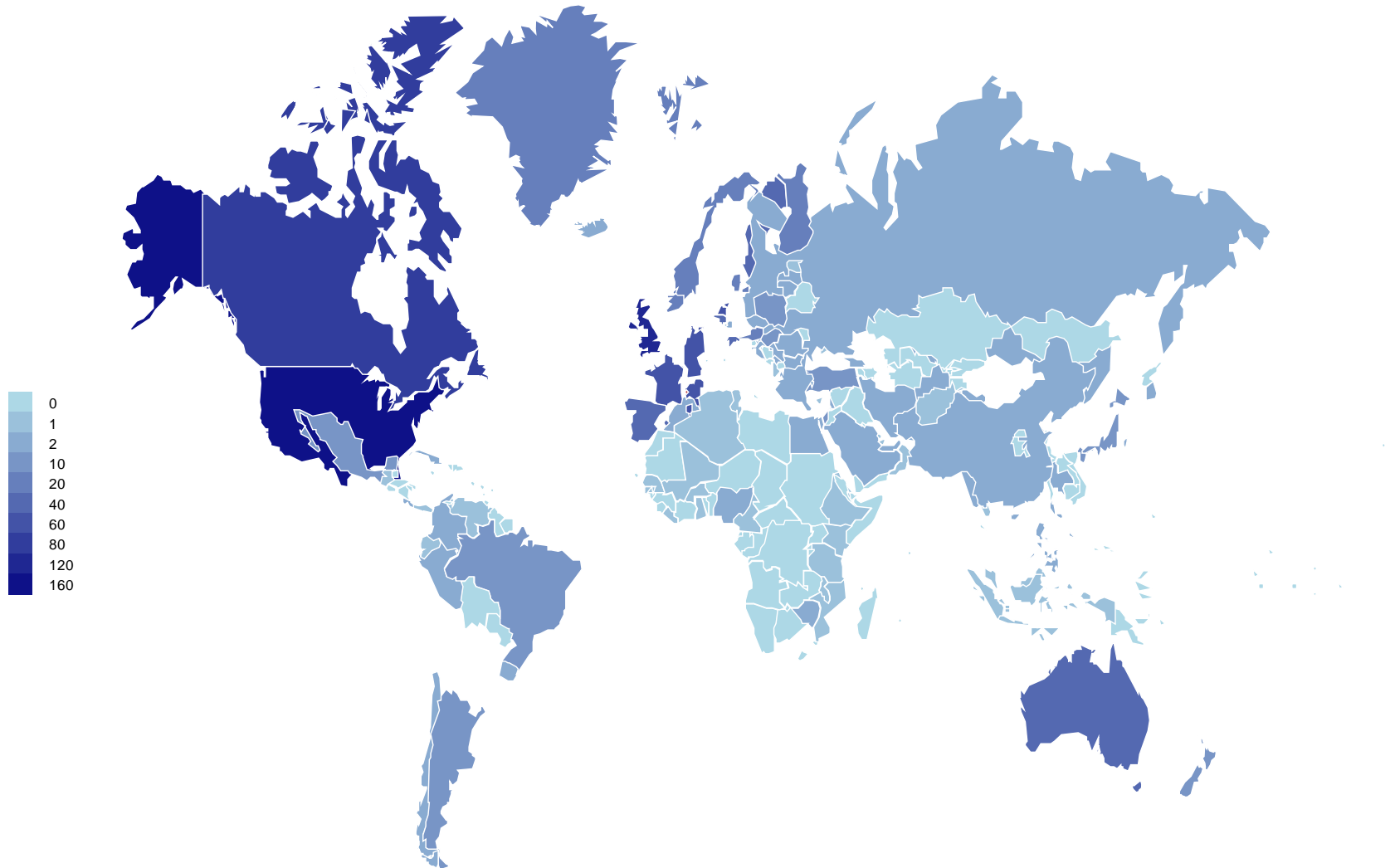
Policy makers

Researchers in the field

COS for routine care

- COS for clinical research: n = 229 studies (87%)
- COS for clinical research and clinical practice: n = 35 studies (13%)
- Ongoing studies: **36%** for research and practice
- The 2017 EULAR recommendations for a core dataset to support observational research and clinical care in rheumatoid arthritis. ARD 2018

Achieving global consensus



Save the date

We are pleased to announce the 7th Meeting of the COMET Initiative

**Thursday 15th and Friday 16th
November 2018**

**Rode Hoed,
Amsterdam**

More details and registration to follow





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