EHDEN
EUROPEAN HEALTH DATA & EVIDENCE NETWORK

The 2nd EHDEN-OHDSI Study-A-Thon
The true story …

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OHDSI EUROPE
OBSERVATIONAL HEALTH DATA SCIENCES AND INFORMATICS

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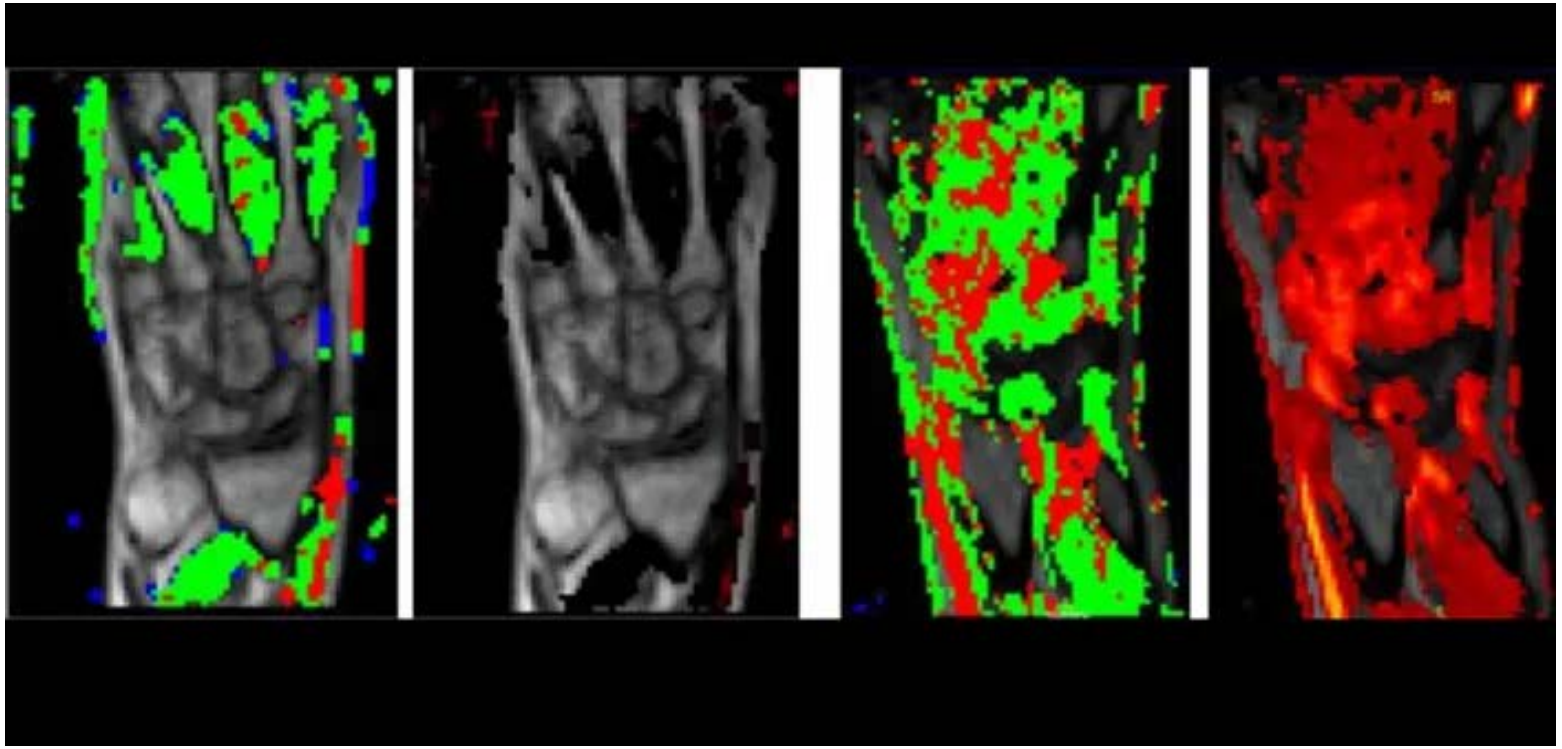
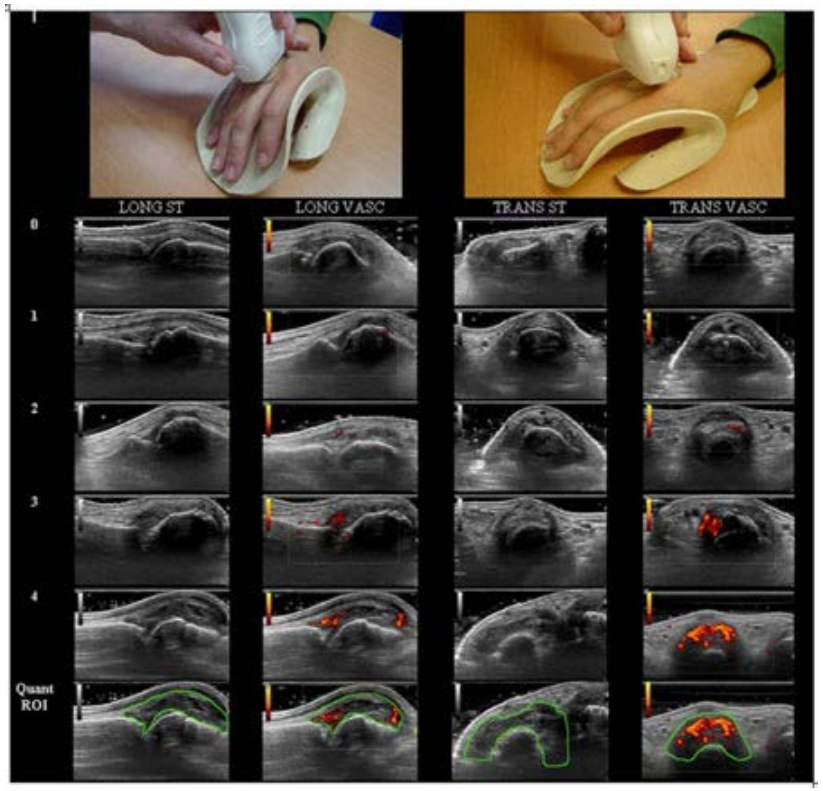
THE VILLAIN … RHEUMATOID ARTHRITIS (RA)



RA

- RA affects 0.5-1%
- Auto-immune -> antibodies against your own joints (and bones, and vessels...)
- Loads of treatments available
- Heterogeneity in guidelines (and potentially in care?)



Seymour et al. Arthritis Research & Therapy 2012 14:R19

eular

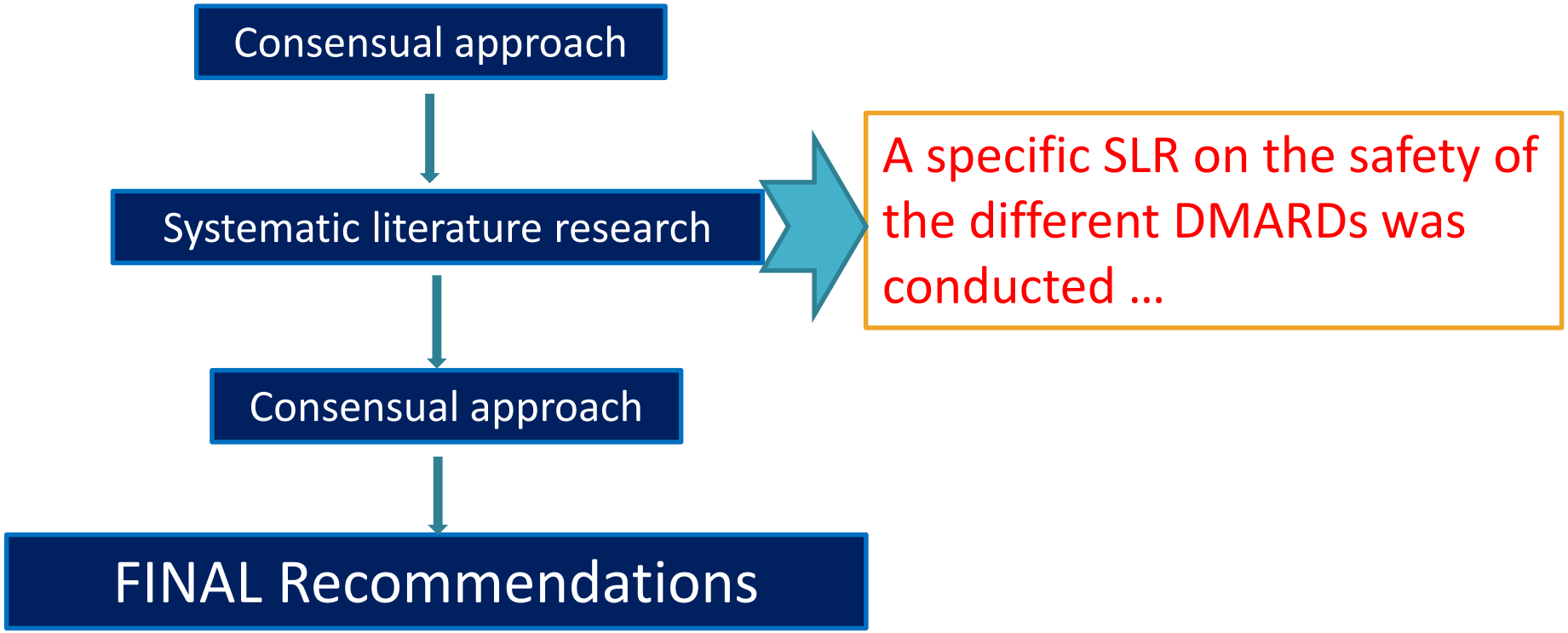
fighting rheumatic & musculoskeletal diseases together

We knew this was coming…
After 7 years of silence …

EULAR recommendations for the management of rheumatoid arthritis – 2019 Update
Smolen J et al. Ann Rheum Dis 2020 Feb

EULAR 2019 RA Guidelines: Methods/methodological approach

- Methods: According to the EULAR Standardized Operating Procedures*



* van der Heijde *et al* Ann Rheum Dis 2016,75:3-15

Review

Safety of synthetic and biological DMARDs: a systematic literature review informing the 2019 update of the EULAR recommendations for the management of rheumatoid arthritis

Alexandre Sepriano [1,2] Andreas Kerschbaumer [3] Josef S Smolen,[3,4] Désirée van der Heijde [1] Maxime Dougados,[5,6] Ronald van Vollenhoven,[7] Iain B McInnes,[8] Johannes W Bijlsma,[9] Gerd R Burmester,[10] Maarten de Wit [11] Louise Falzon,[12] Robert Landewé[13,14]

- Just published this week ….
- RCT and (loads of) Observational Data ….
- But not much on the comparative safety of csDMARDs

EULAR 2019 RA Guidelines: TOP RECOMMENDATIONS

Individual Recommendations 1-4

Recommendations 1-5 – 2019	
1.	Therapy with **DMARDs should be started as soon as the diagnosis of RA is made**. (A)
2.	Treatment should be aimed at reaching a target of sustained remission or low disease activity in every patient. (A)
3.	Monitoring should be frequent in active disease (every 1-3 months); if there is no improvement by at most 3 months after the start of treatment or the target has not been reached by 6 months, therapy should be adjusted. (B)
4.	**MTX should be part of the first treatment strategy.** (A)

STUDY AIMs

1. To characterise treatment patterns in rheumatoid arthritis*, in actual practice, in as many countries as possible... -> DUS*
2. To assess the comparative safety of alternative first-line csDMARD treatment strategies commonly used in rheumatoid arthritis -> *Population-level estimation (PLE)*
3. To predict the risk of safety outcomes for individuals initiating treatment with csDMARDs -> *Patient-level prediction (PLP)*

THE HEROES … A BRILLIANT TEAM!

… WORKING REAL HARD!

… WORKING REAL HARD!

OUR WEAPONS: TONES OF AWESOME DATA!

- IQVIA-provided data in ATLAS:

Country	Dataset Name	Patient #
Australia	LPD EMR	6.16 M
Belgium	LPD EHR	2.34 M
France	Disease Analyser EHR	7.10 M
France	LPD EHR	7.8 M
Germany	Disease Analyser EHR	38.7 M
US	Ambulatory EMR	~73 M
US	Hospital Charge Data Master	91.4 M

AND EVEN MORE DATA!

- **EHDEN** partners in the room:
  - SIDIAP-CMBD (primary care and linked hospital from Catalonia)
  - IPCI (primary care from the Netherlands)
  - Estonian central e-health database

- With remote access for J&J team
  - MarketScan CCAE/MDCD/MDCR
  - Optum ClinFormatics, Optum EHR

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PREP WORK

EUROPE

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APPROVED (HIGH LEVEL) PROTOCOL

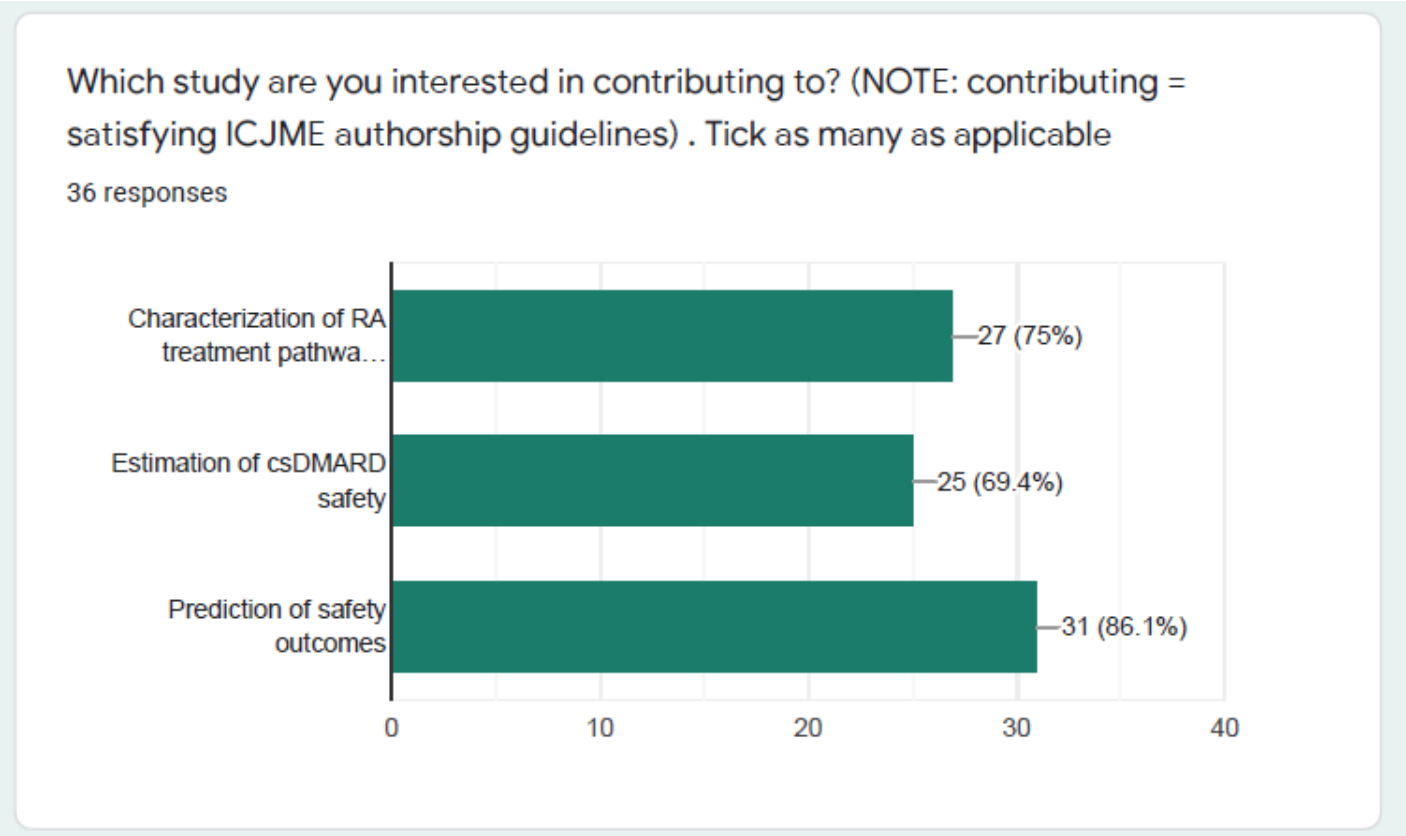
- **Utilisation and comparative safety of disease-modifying anti-rheumatic drugs (DMARDs) for the treatment of rheumatoid arthritis: protocol for a multi-database real-world cohort study**
- AUTHORS: Ed Burn, Anthony Sena, Talita Duarte-Salles, Meghna Jani, Peter Rijnbeek, Patrick Ryan, and Dani Prieto-Alhambra + Other contributors/reviewers [tbc]

- Previously approved by SIDIAP (ES), IPCI (NL) and THIN (UK)

GOOGLE FORM -> DATA, INTERESTS, SKILLS, ...

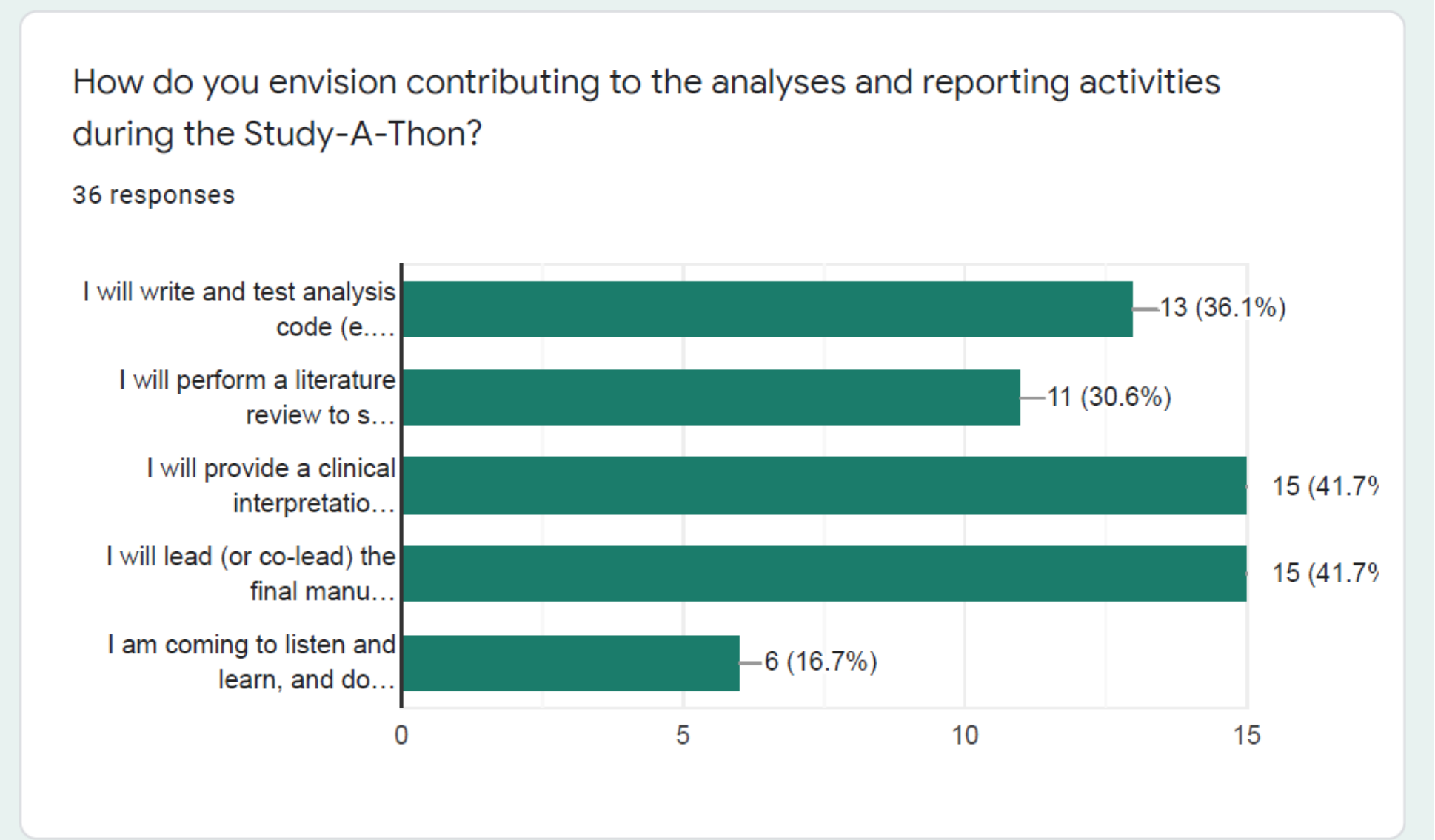
Three teams:

1. DUS
2. PLE
3. PLP



All three of interest (at least to all of us) ☺

THE BEAUTY OF MULTIDISCIPLINARY COLLABORATION



THREE WORKING TEAMS WITH CLEAR TASKS

- DUS -> A Sena
- PLE -> Ed + J Weaver
- PLP -> Cynthia

- Dani + Patrick to lead DUS/PLE
- Peter (Rijnbeek) to lead PLP
- Volunteers to co-lead (left) will be recognised as first/joint first authors

TEAMS AND TASKS - DUS

- **Dani/Patrick** to co-ordinate
- **A Sena** to lead/co-lead abstract+paper

- DN and NH -> literature review AND writing of Background
- KV and KC -> clinical interpretation AND Discussion/Conclusions
- A Sena, C, Y -> R coding/analytics AND Methods and Results

TEAMS AND TASKS - PLE

- **Dani/Patrick** to co-ordinate
- **Ed Burn** and **James W** to lead/co-lead abstract+paper

- AP, R, DV -> literature review AND writing of Background section
- L, D, JL, EB -> clinical interpretation AND Discussion/Conclusions
- James W, Ed B, R, H to lead on R coding/analytics AND writing of Methods and Results

TEAMS AND TASKS - PLP

- **P Rijnbeek** to co-ordinate
- **Cynthia** to lead/co-lead abstract+paper

- A, W, E, L-> literature review AND writing of Background section
- W, M, T > clinical interpretation AND Discussion/Conclusions
- C, W, J, S, R -> R coding/analytics AND Methods and Results

THE AGENDA WE DID NOT FOLLOW…

Monday 13/01/2020

- Introduction to ATLAS & clinical problem
- Cohort definitions for 1 vs 2/3
- Review of cohort/s and start DUS
- Finalise study protocols

Tuesday 14/01/2020

- Review DUS
- Finalise PLE design
- Registration of final protocols (EU PAS)

Wednesday 15/01/2020

- PLE diagnostics and further analytics
- Finalise PLP design
- Draft DUS abstract/s and manuscript/s

Thursday 16/01/2020

- Review PLE and PLP results
- Draft PLE and PLP abstracts and manuscripts

Friday 17/01/2020

- Final tweaks, conclusions, outputs
- Plan/s for completing **publications**
- Closure

(EHDEN-OHDSI 2nd Study-a-thon, Barcelona, January 2020)

TO BE CONTINUED …