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

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THE VILLAIN ... RHEUMATOID ARTHRITIS (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
We knew this was coming...
After 7 years of silence ...

EULAR recommendations for the management of rheumatoid arthritis – 2019 Update
**EULAR 2019 RA Guidelines: Methods/methodological approach**

- **Methods:** According to the EULAR Standardized Operating Procedures*

  - **Consensual approach**
  - **Systematic literature research**
  - **Consensual approach**
  - **FINAL Recommendations**

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

<table>
<thead>
<tr>
<th>Recommendations 1-5 – 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Therapy with <strong>DMARDs should be started as soon as the diagnosis of RA is made.</strong> (A)</td>
</tr>
<tr>
<td>2. Treatment should be aimed at reaching a target of sustained remission or low disease activity in every patient. (A)</td>
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<tr>
<td>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)</td>
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<tr>
<td>4. <strong>MTX should be part of the first treatment strategy.</strong> (A)</td>
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</table>
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:

<table>
<thead>
<tr>
<th>Country</th>
<th>Dataset Name</th>
<th>Patient #</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>LPD EMR</td>
<td>6.16 M</td>
</tr>
<tr>
<td>Belgium</td>
<td>LPD EHR</td>
<td>2.34 M</td>
</tr>
<tr>
<td>France</td>
<td>Disease Analyser EHR</td>
<td>7.10 M</td>
</tr>
<tr>
<td>France</td>
<td>LPD EHR</td>
<td>7.8 M</td>
</tr>
<tr>
<td>Germany</td>
<td>Disease Analyser EHR</td>
<td>38.7 M</td>
</tr>
<tr>
<td>US</td>
<td>Ambulatory EMR</td>
<td>~73 M</td>
</tr>
<tr>
<td>US</td>
<td>Hospital Charge Data Master</td>
<td>91.4 M</td>
</tr>
</tbody>
</table>
• **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
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)
Three teams:

1. DUS
2. PLE
3. PLP

All three of interest (at least to all of us) 😊
How do you envision contributing to the analyses and reporting activities during the Study-A-Thon?

36 responses

- I will write and test analysis code (e.g., 13 (36.1%)
- I will perform a literature review to support the study (11 (30.6%)
- I will provide a clinical interpretation (15 (41.7%)
- I will lead (or co-lead) the final manuscript preparation (15 (41.7%)
- I am coming to listen and learn, and do nothing (6 (16.7%)
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
• **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**
• 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
• 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 ...