Conclusion: Improvements in treatment strategies during the last 25 years have resulted in lower disease activity, less mortality, more DFR and better physical functioning of RA-patients. ACPA+ patients, traditionally the most severe subset, benefited most from these improvements and have become more similar to ACPA- patients.

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OP0024 PATIENT DISCUSSIONS OF GLUCOCORTICOID-RELATED SIDE EFFECTS WITHIN AN ONLINE HEALTH COMMUNITY FORUM

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Background: Social media websites are an important, largely untapped source of data about patients' experience of living with disease and its treatment. This includes information on drugs such as the occurrence, nature and impact of side effects. However, there are few published studies reporting drug safety profiles using such data.
Health Unlocked (HU), Europe's largest social media network for health that supports patients and health care providers, hosts over 200 communities including the UK's National Rheumatoid Arthritis Society (NRAS). Using the example of glucocorticoid (GC) therapy, this study aims to explore the potential of HU posts in providing information about the occurrence and nature of drug side effects.
Objectives:
1. Evaluate the accuracy of a computerised system for automated suspected adverse drug reaction (sADR) detection from posts from HU compared to human annotation.
2. Explore themes of discussion about GC–related ADRs within posts from HU.

Methods: HU provided a dataset of de-identified posts from the NRAS community from December 2015 to December 2016. Posts mentioning GCs were processed by automated Natural Language Processing software, which identified the drug and health issues, mapped them to the Medical Dictionary for Regulatory Activities (MedDRA®) dictionary and categorised as a sADR or not. A sample (n=50) of sADR posts were randomly selected and manually reviewed to determine whether they were true ADRs. Additionally, a sample (n=50) of the posts that included GC and were labelled as having a health issue but not thought to have an ADR, were also assessed for true ADRs.
Posts identified as containing GC ADRs from manual analysis were reviewed to identify themes.
Results: Of the 35,904 posts from 1,998 users, 2,409 posts mentioned GCs, of which 324 posts were identified as containing information representing a sADR.
After manual review of the 50 sampled sADRs, only 36% (18/50) of these posts contained a true ADR. Of the 50 sampled posts that included a mention of GCs and a health issue but were not a sADR, 28% (14/50) were found to contain true ADRs.
Thematic analysis of the 32 posts containing true GC ADRs found the most frequently mentioned ADRs were fractures (n=6), infection (n=5), headaches (n=3) and weight gain (n=3). Posts included rich descriptions about the nature of side effects ("my weight tripled in size with steroids"). This included experiences of how side effects changed with time ("huge mood swings settles after a while"). Users also described how ADRs impacted on their quality of life ("with steroid induced diabetes, I lost a stone in three days, it was grim"), and their value judgements about the importance of side effects ("my taste buds are making everything taste strange, either salty, metallic, or plain awful … but I cope with it, as hardly any pain with steroids.") Posts also described frustrations about how well informed they were about side effects ("I had two eye ops for cataracts, no one told me steroids caused cataracts"). Within posts where ADRs were discussed, patients also commented on the benefits of treatment ("my pain subsided with steroids") and the difficult balance between benefits and harms ("wonderful to not feel like I had RA in the first month of having [pred], but now I have more acne then when I was a teenager").
Conclusion: Current machine learning models for ADR detection in social media still need further improvements to identify sADRs in health forum data. Nonetheless, manual review shows there are important themes relating to patients' experiences and perceptions of using GC that may not be obtained using traditional methods such as analysis of health records or spontaneous pharmacovigilance. With improved automated ADR detection, this rich data source may be useful to identify ADRs most important to patients and the impact on quality of life.

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OP0025 FENEBRUTINIB COMPARED TO PLACEBO AND ADALIMUMAB IN PATIENTS WITH INADEQUATE RESPONSE TO EITHER METHOTREXATE THERAPY OR PRIOR TNF THERAPY: PHASE 2 STUDY

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Background: Fenebrutinib (GDC-0853, FEN) is a small molecule inhibitor of Bruton's Tyrosine Kinase (BTK) that is orally administered, highly selective, non-covalent, and reversible.

Table 1. Endpoints

	Cohort 1, MTX-IR					Cohort 2, TNF-IR	
	FEN-50 50 mg QD (*n*=40)	**FEN-150** 150 mg QD (*n*=109)	**FEN-200** 200 mg BID (*n*=110)	**PBO** (*n*=110)	**ADA** 40 mg Q2W (*n*=111)	**FEN-200** 200 mg BID (*n*=48)	**PBO** (*n*=50)
ACR50 responders at W12	7 (18%)	30 (28%)	38 (35%)	16 (15%)	40 (36%)	12 (25%)	6 (12%)
95% confidence interval (CI)	(6%, 29%)	(19%, 36%)	(26%, 43%)	(8%, 21%)	(27%, 45%)	(13%, 37%)	(3%, 21%)
Weighted difference vs. PBO	8.0%	12.9%	20.0%	-	21.6%	13.9%	-
95% CI of weighted difference*	(-6%, 22%)	(2%, 23%)	(9%, 31%)	-	(11%, 33%)	(-1%, 29%)	-
P-value**	0.2503	0.0164	0.0003	-	0.0001	0.0650	-
Weighted difference vs. ADA	-17.8%	-8.6%	-1.5%	-21.6%	-	-	-
95% CI of weighted difference*	(-34%, -2%)	(-21%, 4%)	(-14%, 11%)	(-33%, -11%)	-	-	-
P-value**	0.0268	0.1694	0.8132	0.0001	-	-	-
DAS28-CRP at W12							
Change from baseline							
Pts (*n*) completing W12	36	95	95	99	104	47	44
Adjusted mean*	-1.74	-1.96	-1.96	-1.33	-2.11	-1.96	-1.20
95% CI of weighted difference*	(-0.93, -0.11)	(-1.00, -0.25)	(-1.00, -0.24)	-	(-1.15, -0.41)	(-1.14, -0.37)	-
P-value vs. PBO**	0.1674	0.0002	0.0002	-	<0.0001	0.0002	-
Safety							
AEs	15 (37.5)	45 (41.3)	56 (50.9)	50 (45.5)	50 (45.0)	11 (22.4)^	22 (44.9)^
Pts with ≥1 event, *n* (%)							
Serious AEs:	-	1 (0.9)	3 (2.7)	1 (0.9)	2 (1.8)	-	-
Pts with ≥1 event, *n* (%)							
Deaths, *n* (%)	-	-	1 (0.9)***	-	-	-	-

*Adjusted for geographic region (Eastern Europe, Latin America, and USA) for Cohort 1, and geographic region and prior exposure to a non-TNF biologic for Cohort 2
**Not adjusted for multiplicity
***Death was due to myocardial infarction
^One PBO pt was treated with FEN-200 in error