

Publication patterns in patient-reported outcomes in original research articles about Diabetes and Inflammatory Bowel Disease

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Background and Objective

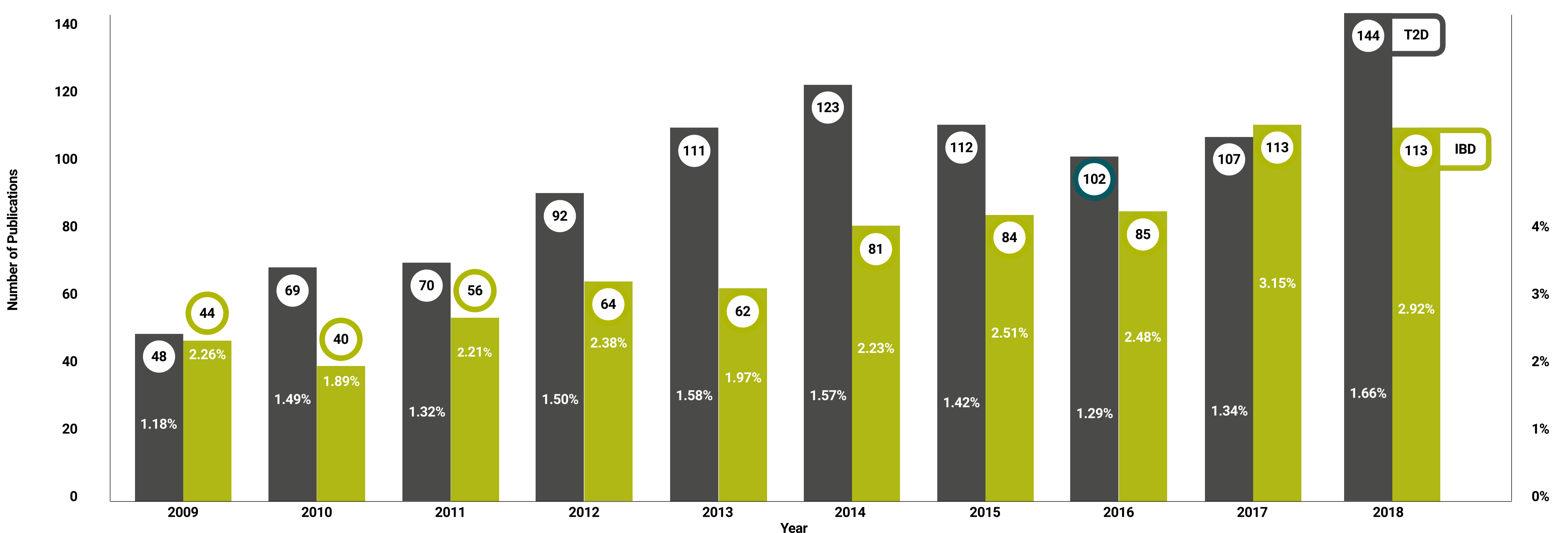
The recent call for action by the FDA and EMA on the use of PRO data to provide evidence of treatment benefit^{1,2} as well as a call for greater data transparency have been important developments in healthcare decision making. The aim of our study was to investigate publication patterns of PRO publications in T2D and IBD

Conclusion

The number of publications describing PROs is increasing, meaning more HRQoL data is available in the literature. However, this increase is not substantially higher than the overall increase in publications since 2009. With an increasing focus on HRQoL and data transparency, there is a need for more PRO-focused publications, especially those targeting payer and decision making audiences

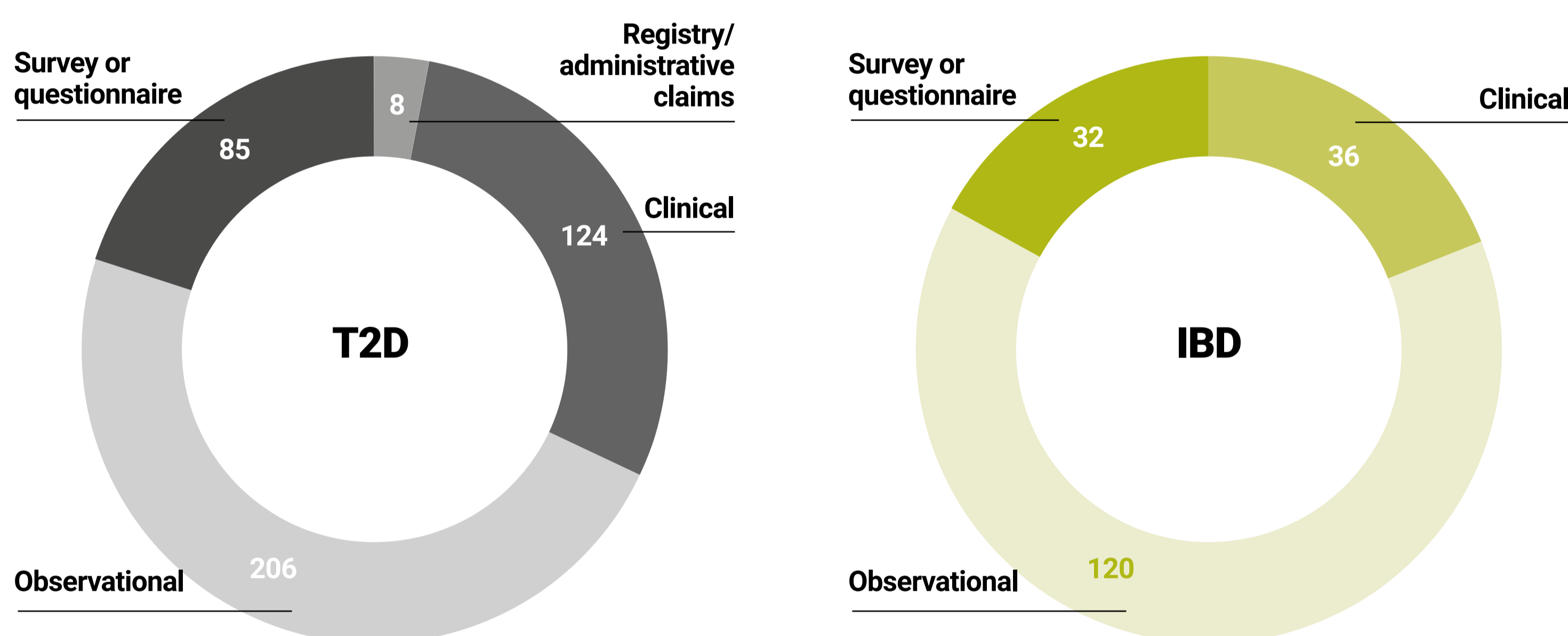
Results

T2D and IBD publications containing PROs increased from 2009–2018

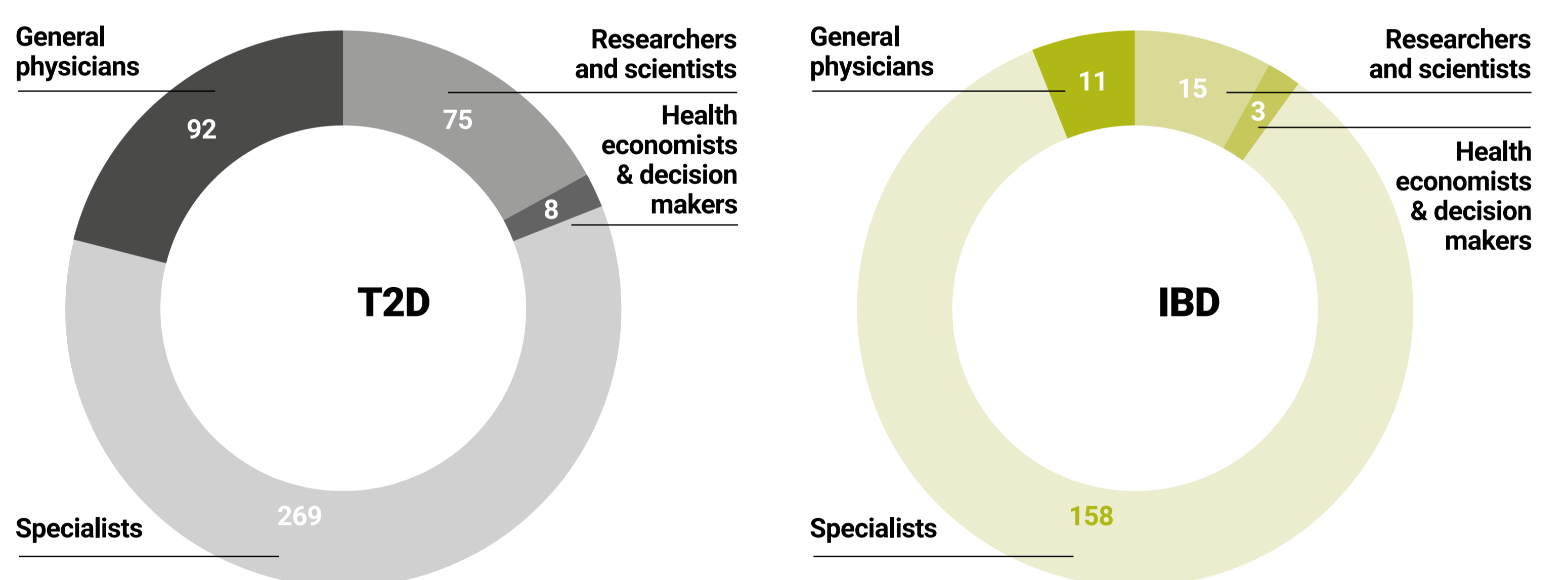


The proportion of PRO publications as a percentage of all publications in that disease area showed a numerical increase in IBD and remained constant in T2D.

PRO data was mostly derived from observational studies, followed by RCTs

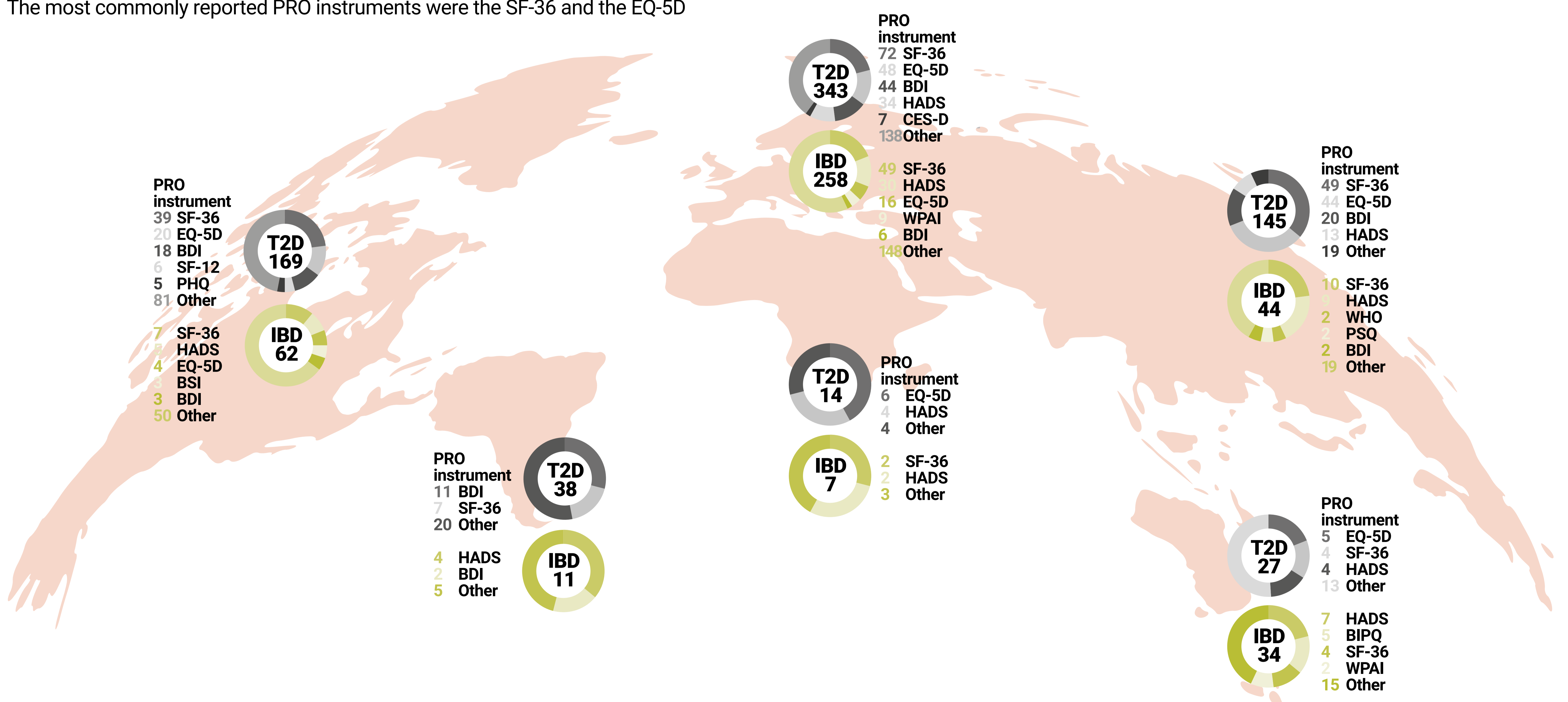


Most PRO publications targeted specialist clinical audiences, with very few targeting health economists or policy and decision makers



Europe had the highest number of PRO publications for both T2D and IBD

The most commonly reported PRO instruments were the SF-36 and the EQ-5D



References
 1. <https://www.fda.gov/downloads/drugs/guidances/ucm193282.pdf>
 2. http://www.ema.europa.eu/docs/en_GB/document_library/Other/2016/04/WC500205159.pdf
 3. Coons, SJ. Pharmacoeconomics. 2000;17:13-35.

Disclosures
 G Richmond, M Diamond, A Houzelle, R Gadiot and T Hartog are employees of Excerpta Medica. For questions please contact g.richmond@excerptamedica.com

Abbreviations
 BDI: Beck Depression Inventory
 BIPQ: Brief Illness Perceptions Questionnaire
 BSI: Brief Symptom Inventory
 CES-D: Center for Epidemiologic Studies Depression Scale
 EMA: European Medicines Agency
 EQ-5D: EuroQoL-5Dimension
 FDA: US Food And Drug Administration

HADS: Hospital Anxiety and Depression Scale
 HRQoL: Health-related quality of life
 IBD: Irritable bowel disease
 PHQ: Patient Health Questionnaire
 PRO: Patient reported outcome
 PSQ: Perceived Stress Questionnaire
 RCT: Randomised controlled trial
 SF-12: 12-Item Short Form Survey
 SF-36: 36-Item Short Form Survey
 T2D: Type 2 diabetes
 WHO: World Health Organization Quality of Life
 WPAI: Work Productivity and Activity Impairment Questionnaire

Methods
 Two therapy areas were selected: T2D and IBD. A literature search was performed using EMBASE to identify original articles containing outcomes from the 7 most commonly used PRO instruments³. A second literature search was performed to identify articles containing outcomes from the additional instruments that were reported ≥ 10 times for T2D and ≥ 5 times for IBD in the initial search. The proportion of PRO publications per year was calculated independently for T2D and IBD, as the percentage of PRO publications within all publications for that therapy area. All publications containing outcomes from commonly used PRO instruments were coded by type of study, audience, country and PRO instrument. As this second analysis focused on HRQoL measures, disease- and symptom-specific PROs were not included. Descriptive statistics were used to compare changes from 2009–2018.