

# Impact of increasing enrollment requirements in administrative claims data

Liza R. Gibbs, BS<sup>1</sup>; Irisdaly Estevez, MPH<sup>1</sup>; Katherine K. Gilpin, BA<sup>1</sup>; Elizabeth M. Garry, PhD, MPH<sup>1</sup>

<sup>1</sup>Aetion, New York, NY

## Background & Objective

- In claims-based pharmacoepidemiology research, a minimum period of observability (typically enrollment) prior to cohort entry should be established to minimize the potential for misclassification of baseline characteristics; ≥6 months is a generally accepted rule of thumb
- Tradeoffs associated with longer enrollment requirements such as impacts to sample size and generalizability have not been fully characterized
- Objective: Evaluate the impact of increasing baseline enrollment requirements on the distribution of baseline characteristics using two claims-based cohorts**

## Methods

**Data:** IBM® MarketScan® commercial and Medicare supplemental claims (Jan 2014 – Sep 2018, U.S.)

### Two separate study cohorts

- Incident rheumatoid arthritis (RA); index date defined as the first of ≥2 RA-related claims ≥7d apart<sup>1</sup>
- Incident chronic obstructive pulmonary disease (COPD); index date defined as first inpatient or first of ≥2 outpatient COPD-related claims 1–365 days apart<sup>2</sup>

Study cohorts were restricted to patients age ≥ 35 years at index. Among each cohort, sub-cohorts were defined which required 6, 12, 18, and 24 months of baseline enrollment prior to index date.

### Analysis

- We assessed demographics on index date and baseline characteristics over respective baseline periods corresponding to the amount of required enrollment (0, 6, 12, 18 and 24 months)
- We calculated absolute standardized differences (ASD) to compare RA and COPD cohorts with 12, 18, and 24 months to 6 months baseline, considering an ASD >0.1 to be a meaningful difference.

Data were analyzed using the Aetion Evidence Platform (AEP)<sup>®</sup>.

## Results

### Patient characteristics

- Among the patients with RA (N=73,595) and COPD (N=211,877), the median [IQR] days of available baseline enrollment was 460 [64 – 992] and 827 [298 – 1,121]
- Relative to patients with no required baseline enrollment, requiring 6 – 24 months **decreased the RA and COPD cohort sizes** by 42.1% – 58.3% and 22.8% – 41.2%, respectively
- Relative to patients with no required baseline enrollment, patients with 24 months tended to be **older** [mean (SD) age in years: 57.82 (12.04) vs 55.39 (11.10) in RA; 66.11 (12.93) vs 63.77 (12.69) in COPD]

### Comorbidities and healthcare resource utilization

- Relative to patients with 6 months required baseline, patients with 24 months were **more likely to have baseline acute respiratory infection** [n (%): 8,780 (20.6%) vs. 15,625 (50.9%) in RA; 45,751 (28.0%) vs 64,988 (52.1%) in COPD] **and hyperlipidemia** [n(%): 11,233 (26.3%) vs. 15,159 (49.3%) in RA; 58,675 (35.9%) vs 75,548 (60.6%) in COPD]
- Relative to patients with 6 months required baseline, patients with 24 months were **more likely to have Medicare benefits** [n (%): 7,861 (18.4%) vs 6,756 (22.0%) in RA; 67,290 (41.1%) vs 58,281 (46.8%) in COPD]
- Baseline total median healthcare cost, annualized to one year, was stable across cohorts, while corresponding baseline mean annualized cost decreased with longer required baseline enrollment

**In our RA and COPD cohorts, patients with longer baseline enrollment requirements were more likely to have prevalent comorbidities captured in respective baseline periods across condition types. Patients with more baseline enrollment also tended to be older and more likely to have Medicare coverage. Median annualized baseline cost was stable across cohorts, while mean annualized costs were more susceptible to shifts due to outlying patients with exceptionally high costs in cohorts with shorter baseline.**

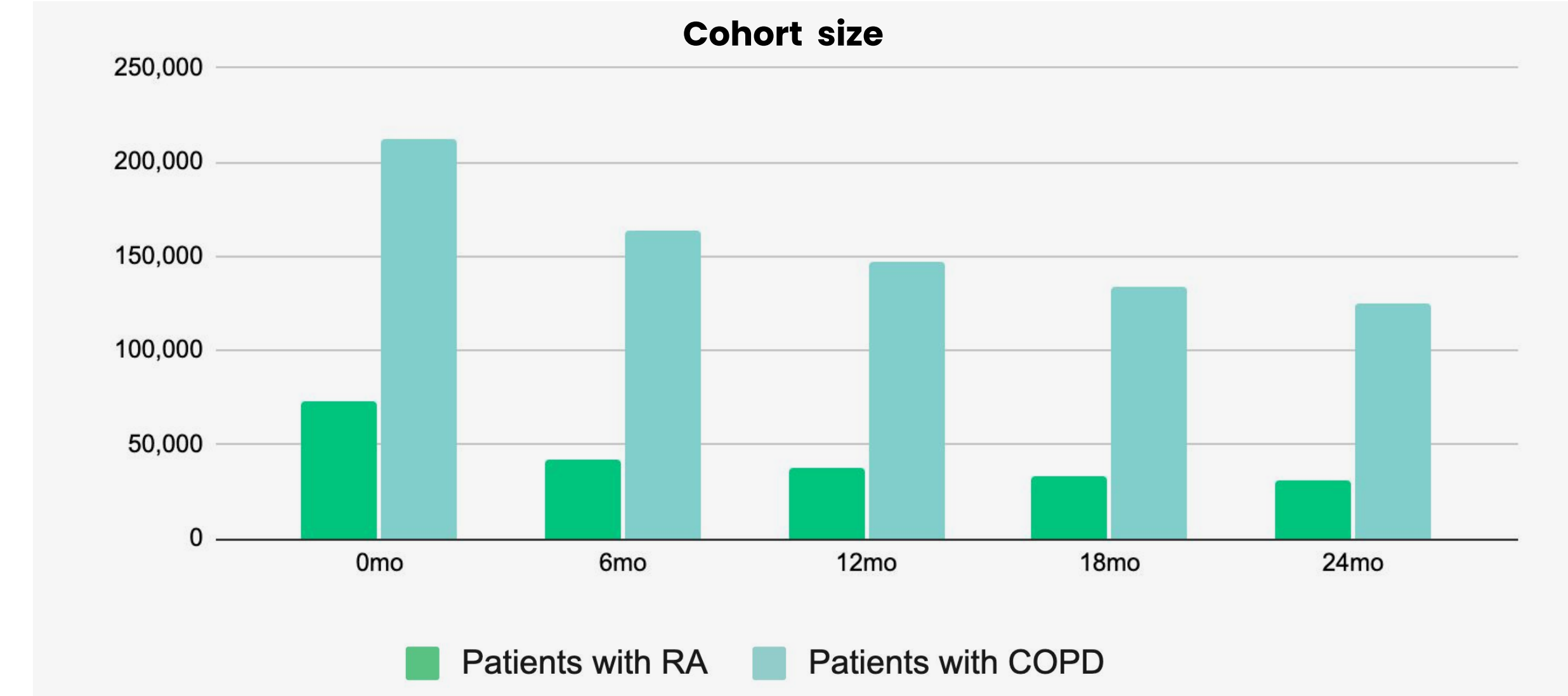


Figure 1. Cohort size by required baseline enrollment among patients with RA and COPD

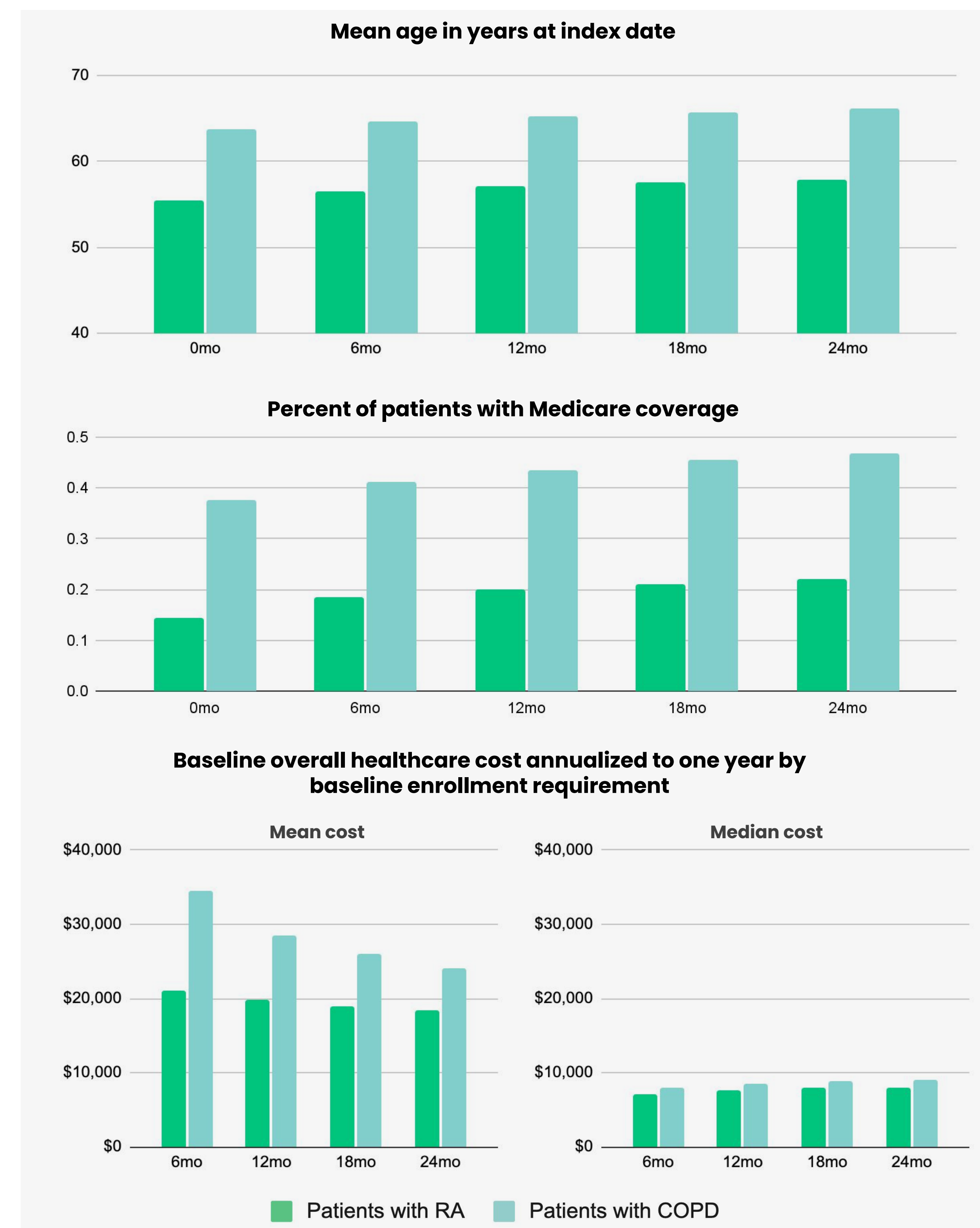


Figure 2. Patient characteristics by required baseline enrollment among patients with RA and COPD

Table 1. Absolute standardized differences by demographics and prevalence of comorbidities in baseline, comparing sub-cohorts with 12, 18, and 24 months of prior enrollment to sub-cohorts with 6 months of prior enrollment

	Demographics				Comorbidities assessed over the respective baseline period (6 months, 12 months, 18 months, or 24 months)																								
	Age	Gender		Payer type		Cardiovascular					Autoimmune and inflammatory					Cancer			Psychiatric		Infections		Metabolic		Respiratory				
	Age in years	Male	Female	Commercial	Medicare	Stroke or TIA	Congestive heart failure	Arrhythmias or cardiac dysrhythmias	Heart disease	Hyperlipidemia	Hypertension	Ankylosing spondylitis	Systemic lupus erythematosus	Psoriasis	Psoriatic arthritis	Sjogren's syndrome	Lung cancer	Colorectal cancer	Any malignant neoplasm	Anxiety	Depression	Acute respiratory infection	Pneumonia	Diabetes, type II	Obesity	Asthma	Obstructive sleep apnea	Smoking-related claim	
RA	12mo vs 6mo	0.04	0.01	0.01	0.04	0.04	0.10	0.06	0.12	0.10	0.25	0.19	0.03	0.07	0.06	0.05	0.03	0.02	0.02	0.11	0.14	0.13	0.30	0.08	0.09	0.18	0.13	0.08	0.12
	18mo vs 6mo	0.08	0.01	0.01	0.07	0.07	0.17	0.09	0.20	0.16	0.38	0.28	0.04	0.11	0.10	0.07	0.05	0.03	0.03	0.17	0.23	0.21	0.51	0.15	0.13	0.27	0.19	0.12	0.21
	24mo vs 6mo	0.11	0.01	0.01	0.09	0.09	0.24	0.12	0.26	0.21	0.49	0.34	0.05	0.14	0.12	0.09	0.06	0.03	0.04	0.23	0.29	0.27	0.67	0.19	0.16	0.33	0.24	0.16	0.28
COPD	12mo vs 6mo	0.05	0.00	0.00	0.05	0.05	0.12	0.07	0.13	0.12	0.26	0.20	0.01	0.03	0.05	0.02	0.02	0.01	0.02	0.10	0.12	0.13	0.23	0.09	0.08	0.14	0.11	0.07	0.16
	18mo vs 6mo	0.09	0.01	0.01	0.09	0.09	0.22	0.12	0.21	0.19	0.40	0.29	0.02	0.05	0.08	0.03	0.03	0.02	0.03	0.17	0.19	0.20	0.39	0.15	0.13	0.22	0.17	0.10	0.27
	24mo vs 6mo	0.11	0.01	0.01	0.11	0.11	0.30	0.16	0.27	0.24	0.51	0.35	0.03	0.07	0.11	0.05	0.04	0.03	0.04	0.23	0.25	0.26	0.51	0.19	0.16	0.28	0.21	0.13	0.37

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## Conclusions

Increasing the length of required minimum enrollment impacts sample size, increases capture of chronic conditions, and may otherwise affect the demographic makeup of a cohort. Descriptive analysis to compare cohort characteristics can help to better understand the bias-precision tradeoff for lengthening enrollment requirements.

## Disclosures

This project was unfunded. Ms. Gibbs, Ms. Estevez, Ms. Gilpin, and Dr. Garry are full-time employees of Aetion Inc. and hold stock options or equity in Aetion.

## References

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