



IMPROVECARENOW

Epidemiology of IBD in Pediatric Patients in the US: Data from the ImproveCareNow Registry

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Overview

- ▶ ImproveCareNow
- ▶ Age, disease type and severity, use of medications
- ▶ Sequential use of biologics
- ▶ Example study population diagrams

ImproveCareNow Learning Health Network

- ▶ Founded in 2007
 - ▶ 109 sites (97 in US)
 - ▶ 950 pediatric gastroenterologists
 - ▶ >85% of patients enrolled
- ▶ Sites *pay* annual participation fee and provide site staffing
- ▶ Registry
 - ▶ 35,000 patients
 - ▶ 250,000 visits
 - ▶ 80,000 patient-years
- ▶ Collect 50 – 75 data elements at each OP visit
 - ▶ Symptoms
 - ▶ Physical findings
 - ▶ Medications
 - ▶ Assessment of disease phenotype, extent, severity
 - ▶ PGA, Short PCDAI, PUCAI, Mayo subscore (SF, RB)
- ▶ Brief CRF for hospitalized patients
- ▶ Data used for clinical care, improvement and research

Analysis

- ▶ Given size of ICN population and diversity of centers, patients are broadly representative of US pediatric IBD population (opinion)
- ▶ Young adults followed at pediatric centers may not be representative of young adult IBD population
 - ▶ Analyses limited to patients/visits prior to 18 years of age
- ▶ ICN not an inception cohort
 - ▶ No data collected about disease severity, phenotype, medication use prior to ICN enrollment

Age at diagnosis

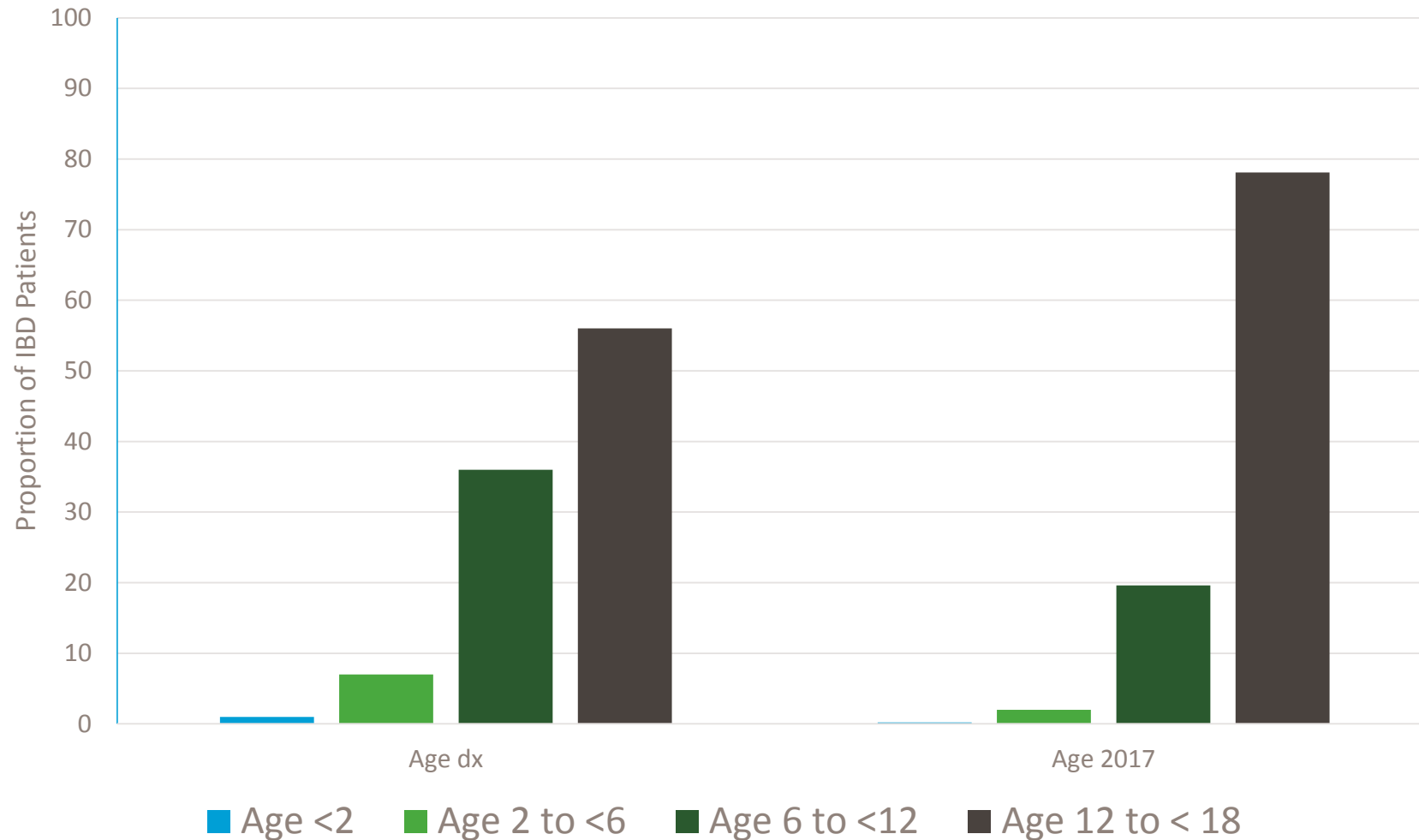
Age group	CD n=21,150 (63%)	UC n=9,549 (29%)	IBD NOS n=2,793 (8%)
<2	205 (1%)	111 (1%)	75 (3%)
2 to <6	1,149 (5%)	1,004 (11%)	345 (12%)
6 to <12	7,959 (38%)	3,043 (32%)	928 (33%)
12 to <18	11,837 (56%)	5,391 (57%)	1,445 (52%)

Age at most recent visit

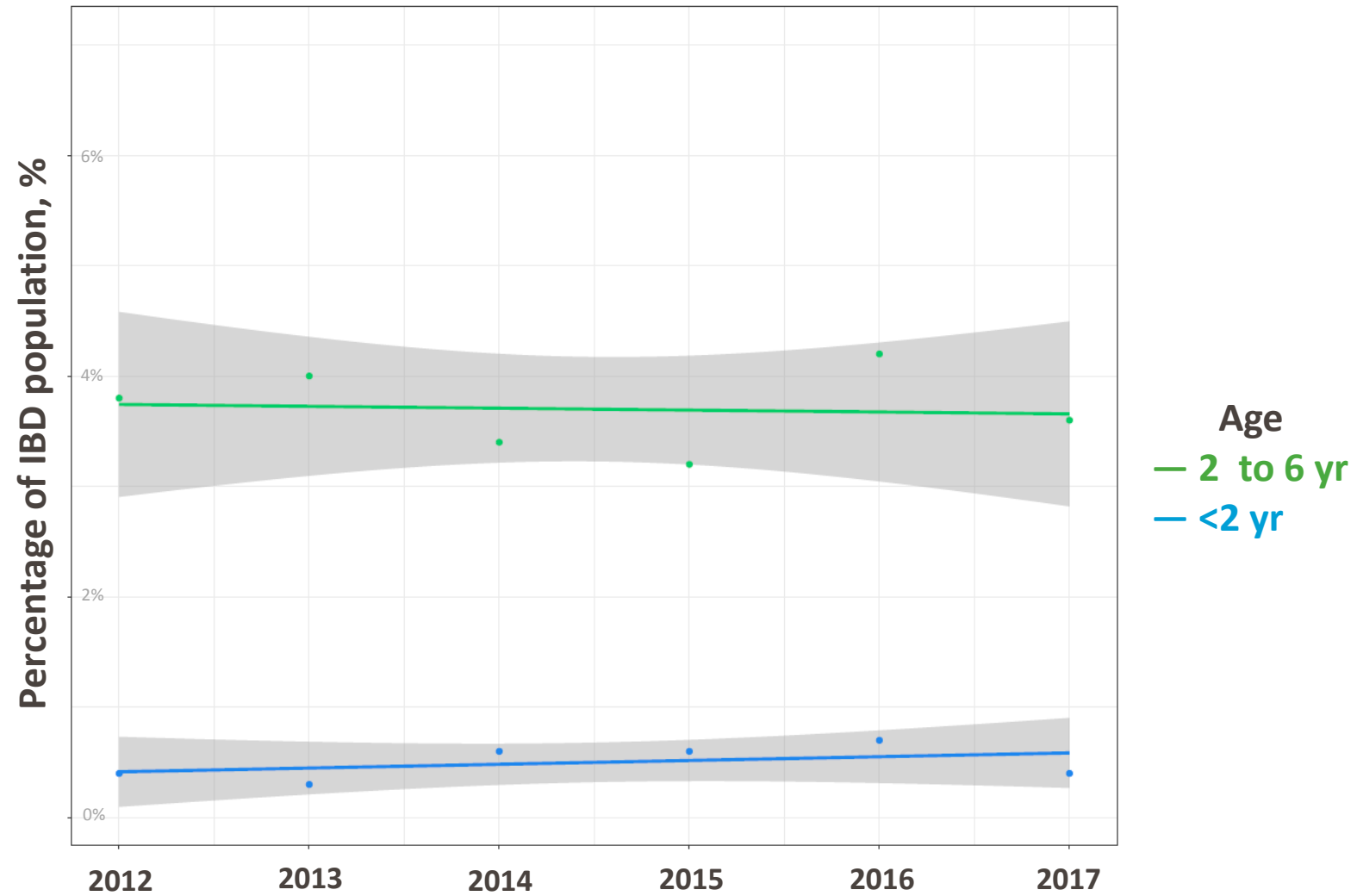
Age group	CD n=8,960 (67%)	UC n=3,640 (27%)	IBD NOS n=853 (6%)
<2	13 (0.1%)	7 (0.2%)	3 (0.4%)
2 to <6	140 (2%)	89 (2%)	62 (7%)
6 to <12	1,638 (18%)	754 (21%)	245 (29%)
12 to <18	7,169 (80.0%)	2,790 (77%)	543 (64%)

Analysis includes patients with a recorded visit in 2017

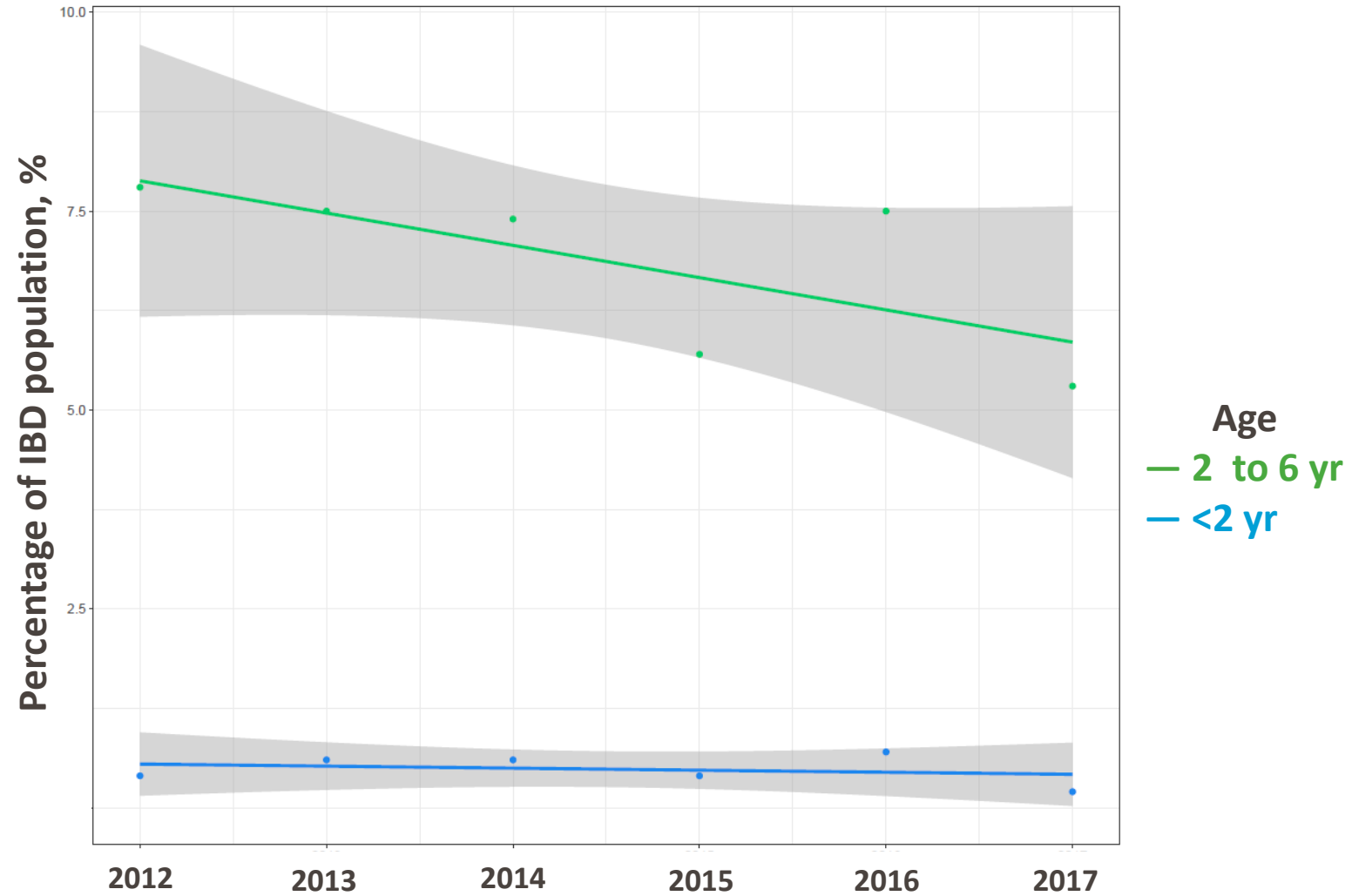
Age at diagnosis vs current age (all IBD)



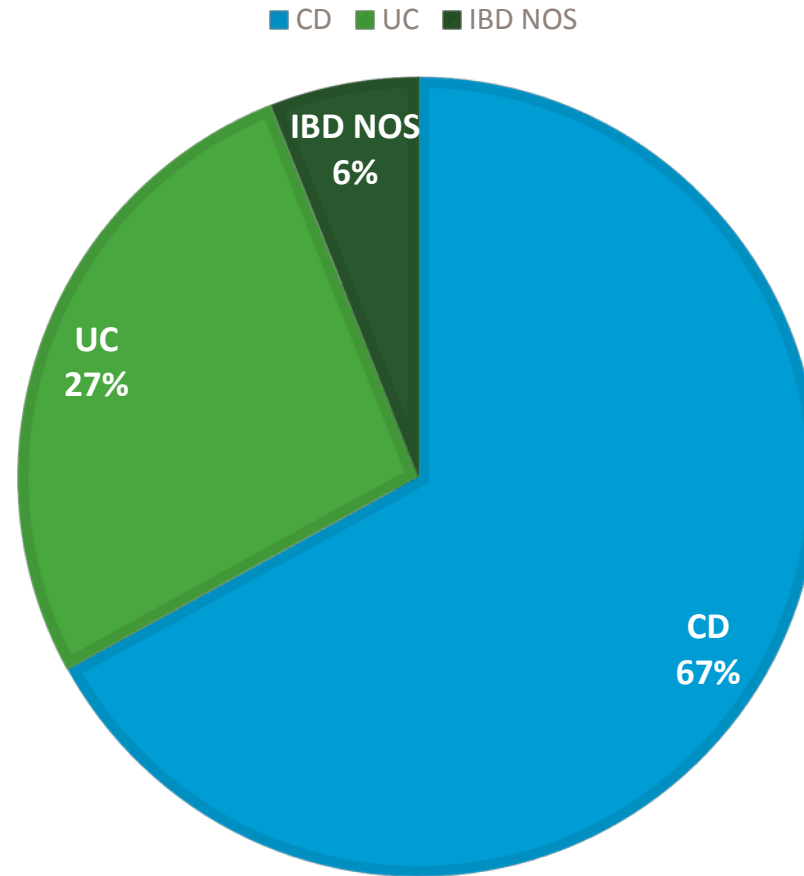
Age at diagnosis over time (CD)



Age at diagnosis over time (UC)

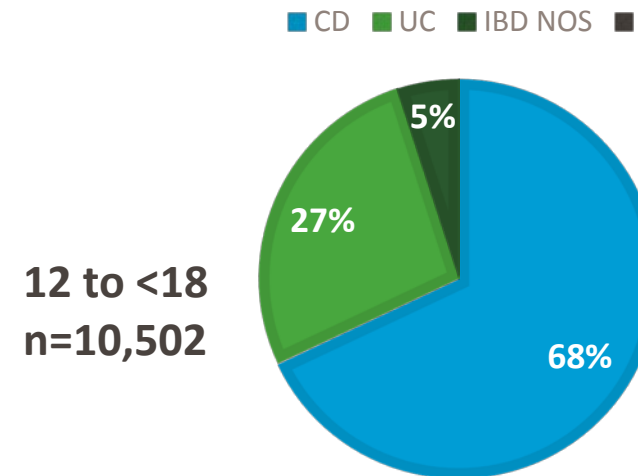
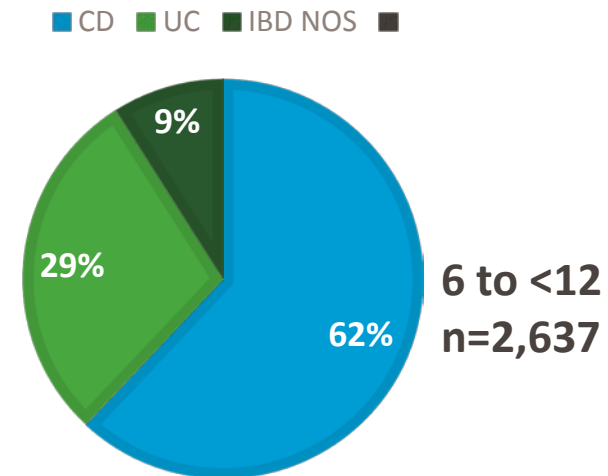
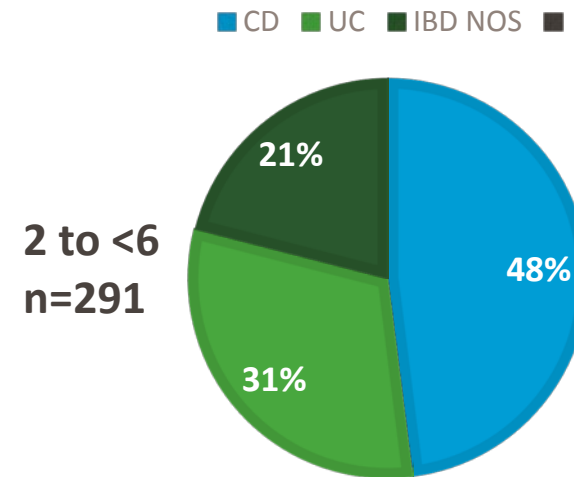
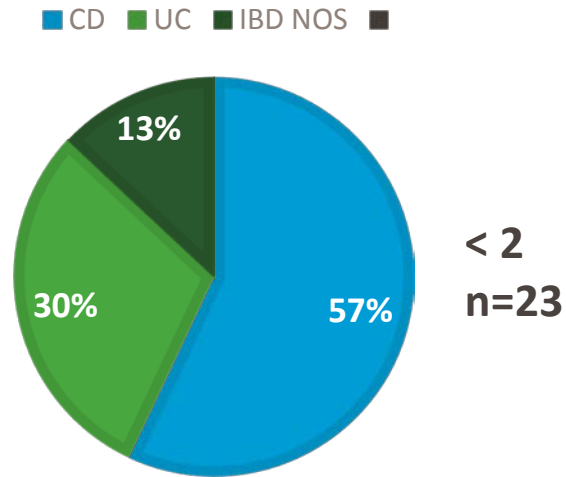


Disease Type at last recorded visit



Analysis includes 13,453 patients <18 years with a recorded visit in 2017

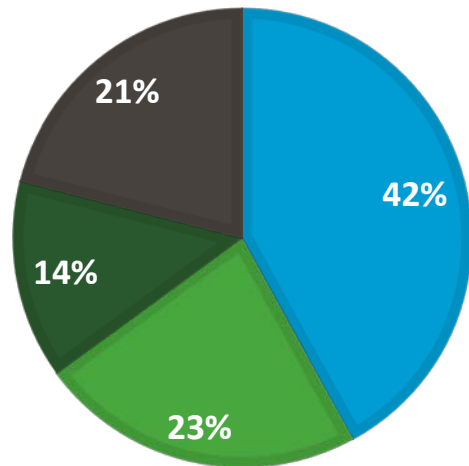
Disease Type at last recorded visit



CD disease severity by sPCDAI

DISEASE ACTIVITY

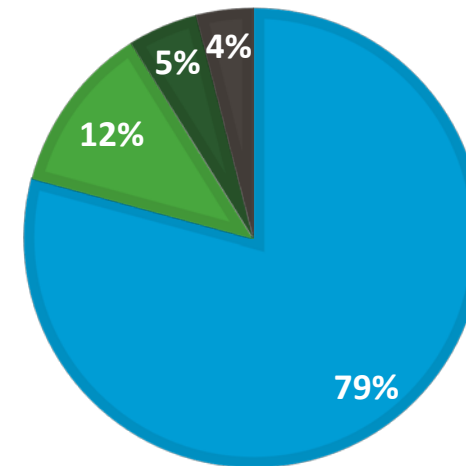
■ Inactive ■ Mild ■ Moderate ■ Severe



Worst ever recorded in Registry (n=8,520)

DISEASE ACTIVITY

■ Inactive ■ Mild ■ Moderate ■ Severe

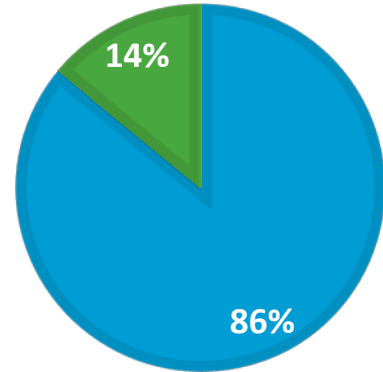


Last recorded visit in 2017 (n=6,460)

CD disease severity by sPCDAI

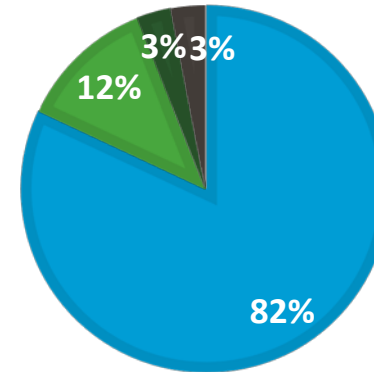
Most recent recorded in 2017

■ Inactive ■ Mild ■ Moderate ■ Severe



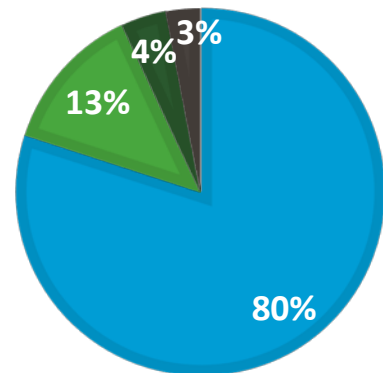
< 2
n=7

■ Inactive ■ Mild ■ Moderate ■ Severe



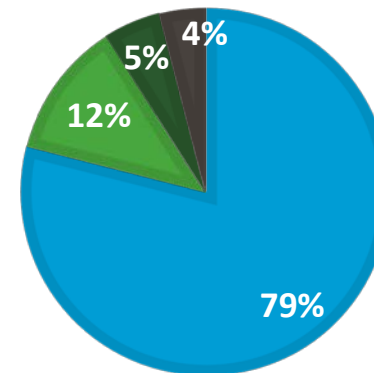
2 - < 6
n=99

■ Inactive ■ Mild ■ Moderate ■ Severe



6 - < 12
n=1,212

■ Inactive ■ Mild ■ Moderate ■ Severe

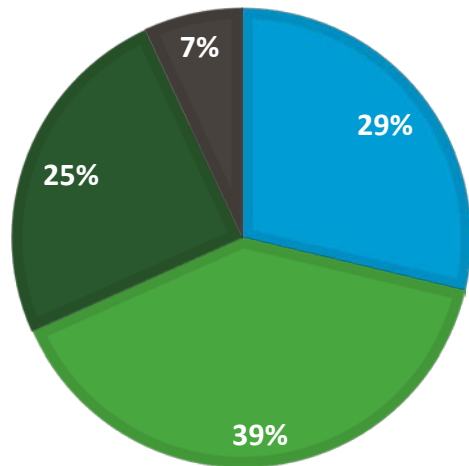


12 - < 18
n=5,142

UC disease severity by PUCAI

DISEASE ACTIVITY

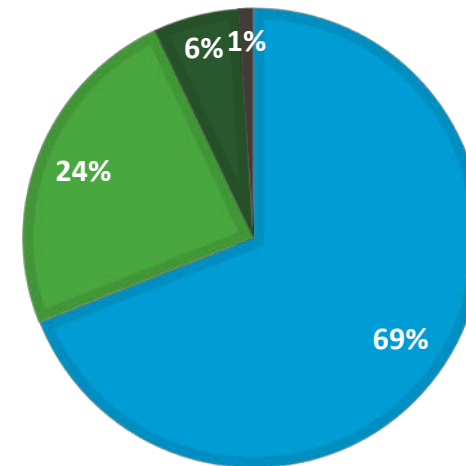
■ Inactive ■ Mild ■ Moderate ■ Severe



Worst ever recorded in Registry (n=3,567)

DISEASE ACTIVITY

■ Inactive ■ Mild ■ Moderate ■ Severe

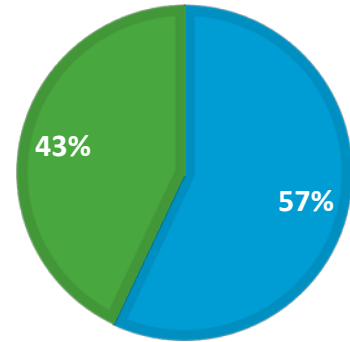


Last recorded visit in 2017 (n=3,399)

UC disease severity by PUCAI

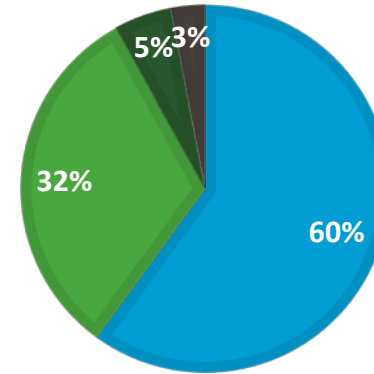
Most recent recorded in 2017

■ Inactive ■ Mild ■ Moderate ■ Severe



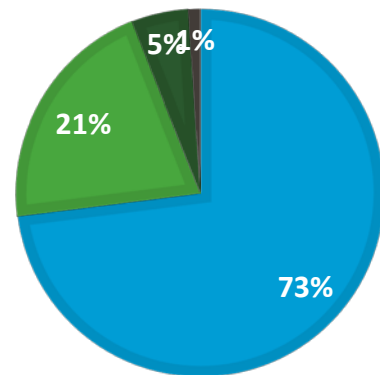
< 2
n=7

■ Inactive ■ Mild ■ Moderate ■ Severe



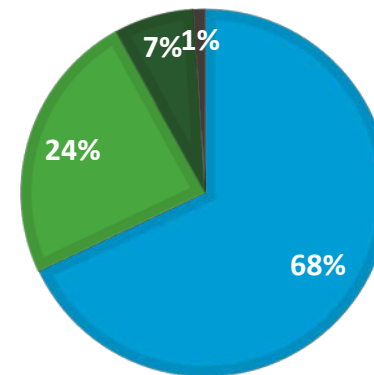
2 - < 6
n=78

■ Inactive ■ Mild ■ Moderate ■ Severe



6 - < 12
n=712

■ Inactive ■ Mild ■ Moderate ■ Severe



12 - < 18
n=2,599

Prednisone use

	Ever recorded n (%)	Recorded at last visit in 2017 n (%)
CD n=8,960	2,999 (34%)	396 (4%)
UC n=3,640	1,615 (44%)	325 (9%)
IBD NOS n=853	349 (41%)	72 (8%)

Analysis include patients with one or more visits in 2017 who were <18 years of age at their last visit

6MP, Azathioprine, or MTX use

	Ever recorded n (%)	Recorded at last visit in 2017 n (%)
CD n=8,960	5256 (59%)	3506 (39%)
UC n=3,640	1562 (43%)	1056 (29%)
IBD NOS n=853	365 (43%)	240 (28%)

Analysis include patients with one or more visits in 2017 who were <18 years of age at their last visit

Biologic use (anti-TNF, ustekinumab, vedolizumab)

	Ever recorded n (%)	Recorded at last visit in 2017 n (%)
CD n=8,960	5991 (67%)	5152 (56%)
UC n=3,640	1372 (38%)	1170 (32%)
IBD NOS n=854	317 (37%)	246 (29%)

Analysis includes patients with one or more visits in 2017 who were <18 years of age at their last visit

Use of sequential biologic agents

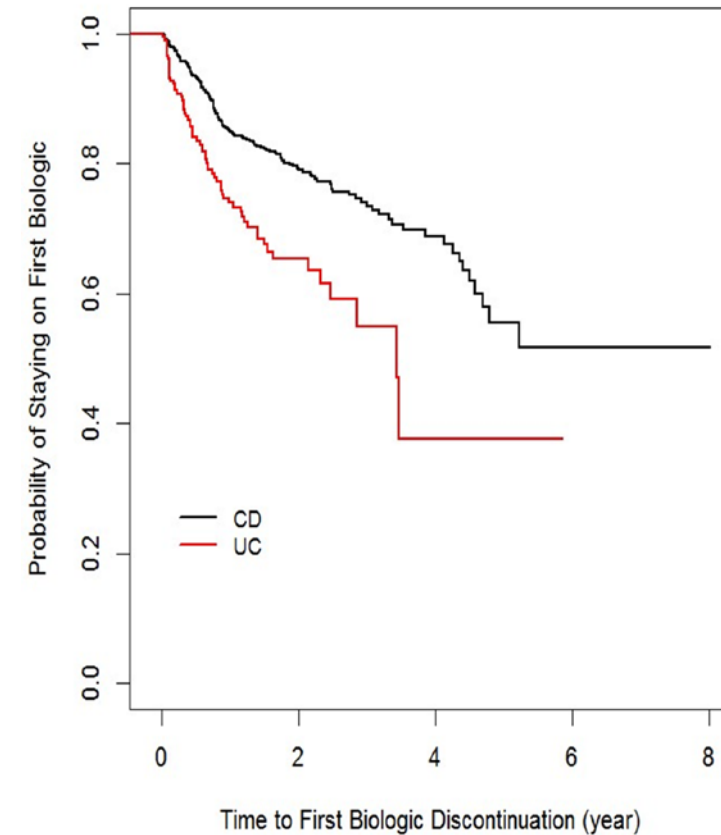
- ▶ Study using data from the ImproveCareNow registry
 - ▶ January 2008 to September 2016
 - ▶ 17,639 patients diagnosed with IBD before age 18
 - ▶ Sponsored by Takeda
- ▶ A subset of 1,029 patients who received their first biologic dose after enrollment into ICN had a **chart review** at 39 ICN centers in the US to obtain additional clinical information
 - ▶ Use and timing of medications prior to enrollment in ICN

Use of sequential biologic agents

- ▶ Median time from diagnosis to 1st biologic agent:
 - ▶ CD: 325 days
 - ▶ UC: 425 days
- ▶ The first biologic agent was an anti-TNF agent in 100% of cases

Persistence on 1st anti-TNF

Group	CD	UC
% remaining on 1 st anti-TNF:		
12 months	85%	75%
24 months	79%	66%
36 months	74%	55%

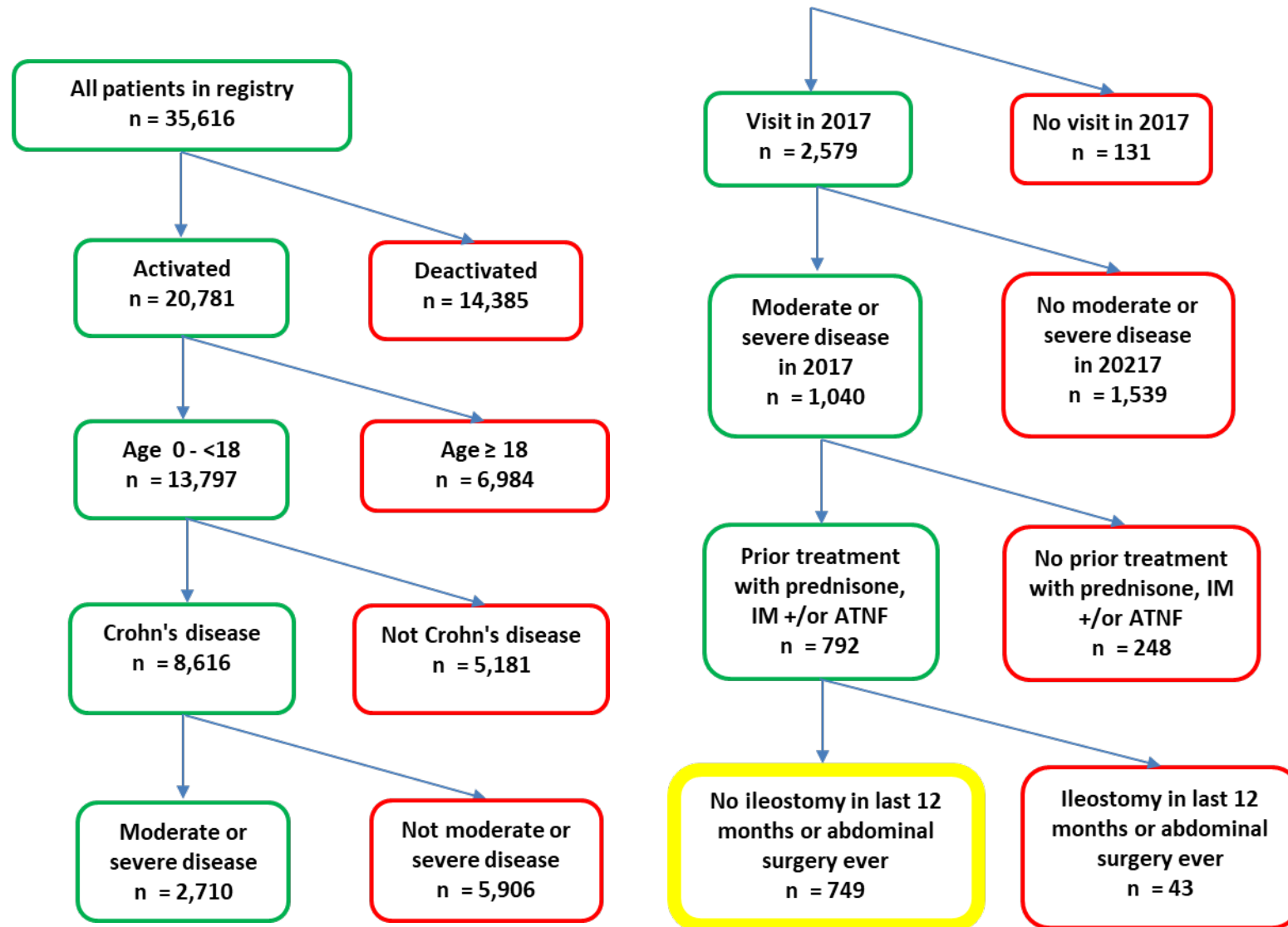


Frequency of multiple biologic agent use in biologic agent exposed patients

		% of IBD patients	% of CD patients	% of UC patients
# BAs used ^c	≥ 2	17%	16%	20%
	≥ 3	2%	2%	3%

^c Median follow up = 1.56 years (IQR: 0.89 – 2.57 years)

Example CD trial population diagram

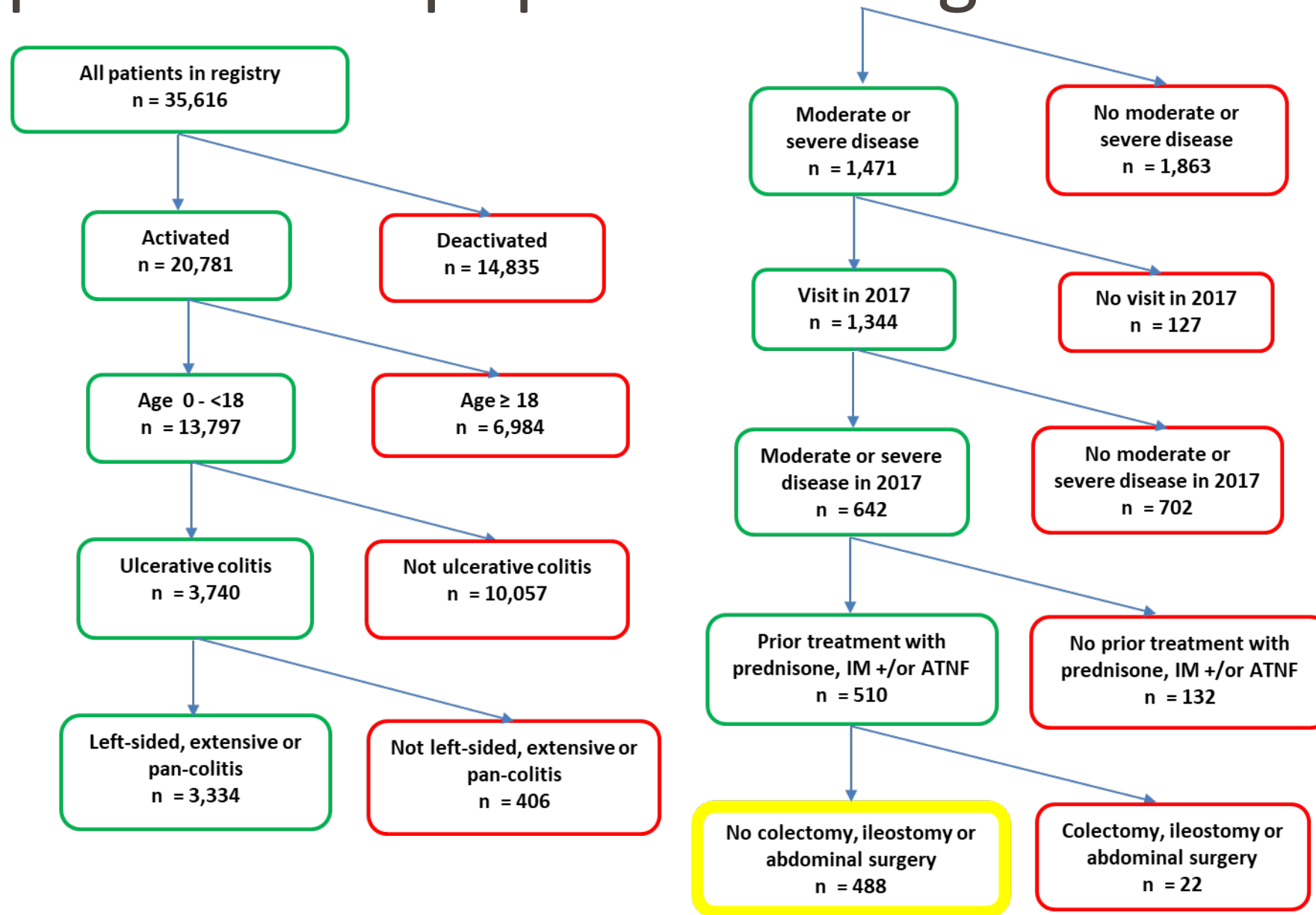


CD trial population stratified by age and ATNF use

Crohn's disease n = 749

Age (Yr)	ATNF treatment		Total
	No (n, %)	Yes (n, %)	
<2	0	0	0
2 - <6	0 (0%)	6 (100%)	6
6 - <12	30 (25%)	89 (75%)	119
12 - <18	144 (23%)	480 (77%)	624
Total	174 (23%)	575 (77%)	749

Example UC trial population diagram



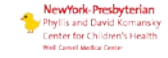
UC trial population stratified by age and ATNF use

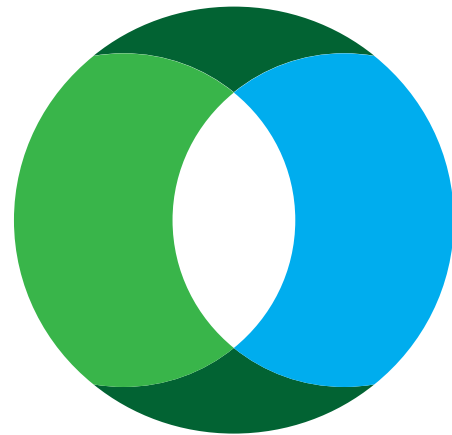
Ulcerative colitis n = 488

Age (Yr)	ATNF treatment		Total
	No (n, %)	Yes (n, %)	
<2	0	0	0
2 - <6	6 (50%)	6 (50%)	12
6 - <12	42 (45%)	51 (55%)	93
12 - <18	174 (45%)	209 (55%)	383
Total	222 (45%)	266 (55%)	488

Conclusions

- ▶ ~80% of pediatric IBD patients are 12 to 17 years of age
 - ▶ ~20% age 6 to 11 years
 - ▶ <6 years is rare
- ▶ CD to UC ratio is 2.5:1
- ▶ Many patients have moderate-severe disease activity at some point in their disease course
 - ▶ ~70% - 80% of patients in clinical remission at any given time
 - ▶ ~5% - 10% have moderate to severe disease activity
- ▶ ~ 50% patients IM experienced; 50% biologic experienced
- ▶ Persistence on 1st anti-TNF for CD: 74% at 3 years
 - ▶ Somewhat lower for UC
- ▶ Large, multicenter registry can be used to estimate number of patients who may meet inclusion/exclusion criteria for a trial





IMPROVE**CARE**NOW

Improvement, Discovery, Innovation

Race and ethnicity (patients < 18 at time of registration)

Race	CD (n=21,150)	UC (n=9,549)	IBD NOS (n=2,793)
White	14761 (82%)	6434 (82%)	1857 (81%)
Black	1991 (11%)	728 (9%)	243 (11%)
Asian	442 (2%)	249 (3%)	76 (3%)
Other	742 (4%)	475 (6%)	110 (5%)

Ethnicity	CD (n=21,150)	UC (n=9,549)	IBD NOS (n=2,793)
Latino	890 (6%)	788 (12%)	162 (8%)
Not Latino	14026 (94%)	5800 (88%)	1949 (92%)