

# The Treatment Naïve UC patient -Case Study



35 year old female  
Advertising executive.  
Non-smoker

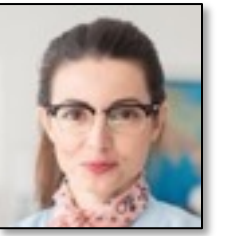
Meet: Catherine

# Disclosures

## Tim Raine

**Has received research/educational grants and/or speaker/consultation fees from:**

Abbvie, Arena, Aslan, AstraZeneca, BMS, Celgene, Ferring, Galapagos, Gilead, GSK, Heptares, LabGenius, Janssen, Mylan, MSD, Novartis, Pfizer, Sandoz, Takeda and UCB



# Case: Catherine

## Case History

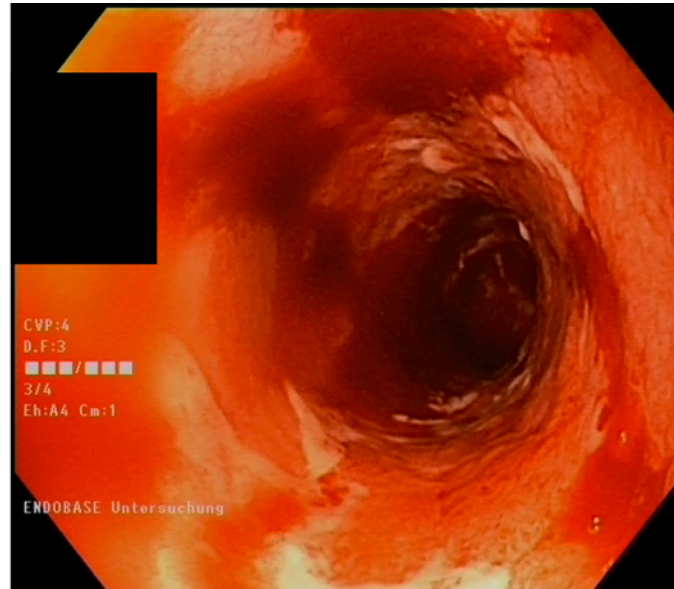
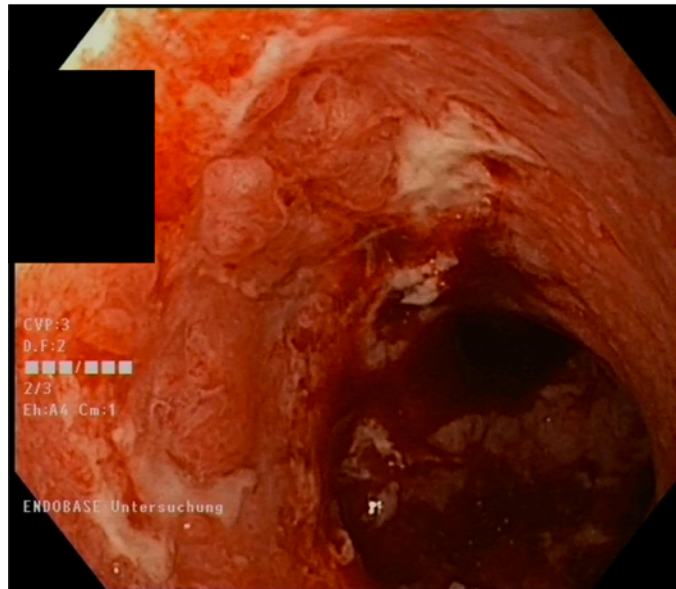
Left sided (E2) ulcerative colitis diagnosed in 2011

2011: Initially treated with oral/rectal 5-ASA with no help.

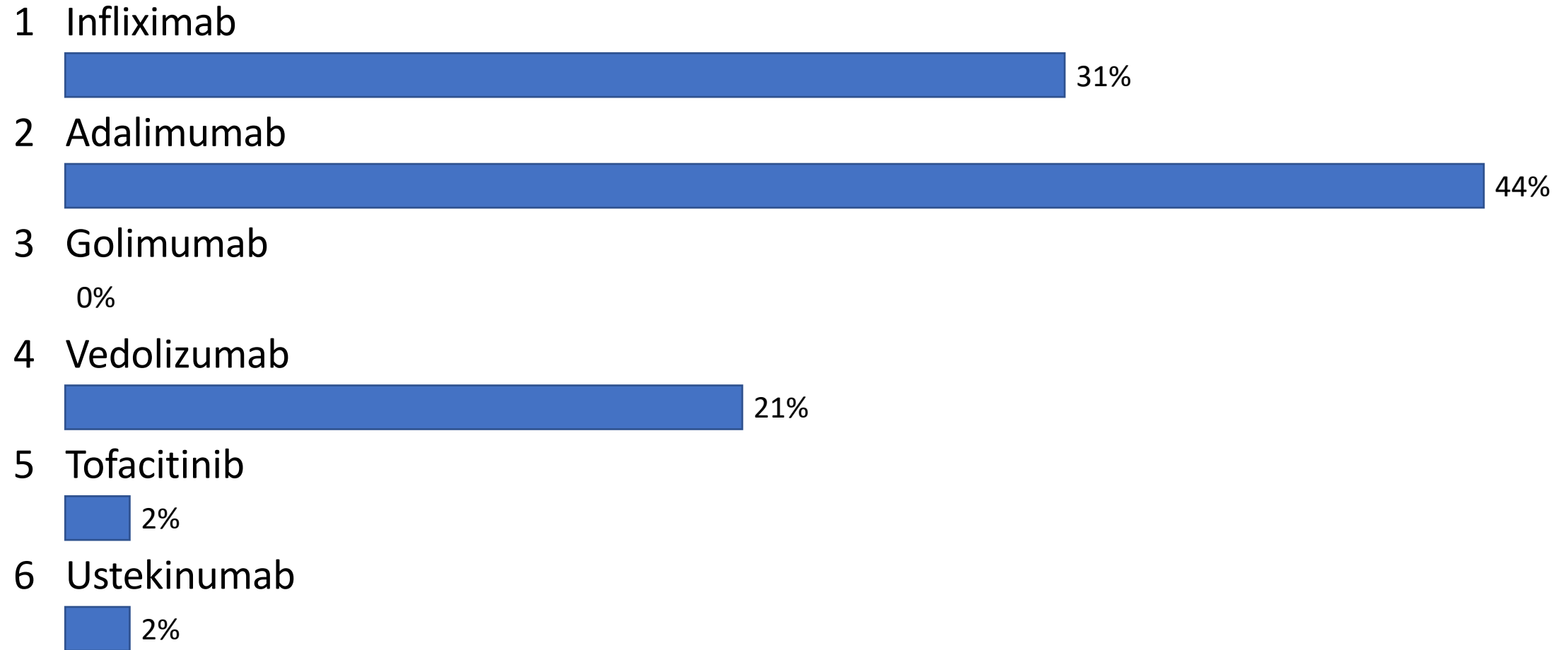
Pancreatitis with azathioprine.

# Left-sided UC in a 35-year old female patient

- Steroid-dependent, left-sided UC
- Currently 10-12 stools per day (1 nocturnal)
- Blood in majority of stools
- fCal > 2100  $\mu\text{g/g}$ , CRP 40 mg/dl, WBC 12, Hb 9 g/dl
- Intolerant of azathioprine (pancreatitis)



Please vote  
What is the “right” drug to use here?



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# Colectomy?

*“No attempt is made here to suggest that total colectomy is the final word on treatment for ulcerative colitis, nor even to insinuate that it is the right treatment for the majority of patients suffering from this disease. However, when a ship is foundering, a life boat, though neither pleasant nor agreeable, may be the only hope.”*

	HODaR (EQ-5D)		Arseneau (TTO)	
	Mean	SD	Mean	SD
Remission	0.88	0.14	0.79	0.24
Active UC	0.42	0.32	0.32	0.31
Surgical remission	0.60	0.38	0.63	0.30
Surgical complications	0.42	0.32	0.49	0.32

***The Committee concluded that a drug treatment that improves or brings the disease into remission would have a major effect on quality of life, and that avoiding surgery was important to people with ulcerative colitis.***

# Evolving treatment landscape in IBD

**UC**

**IBD**

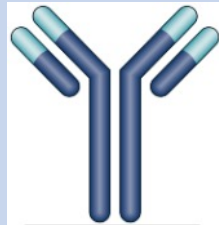
**CD**

**2<sup>nd</sup> generation  
biologics**

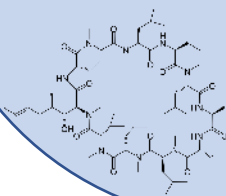
**Anti-TNF  
biologics**

**Small  
molecules**

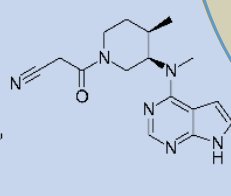
Golimumab



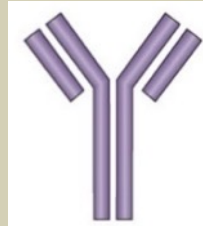
Ciclosporin



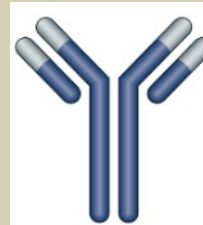
Tofacitinib



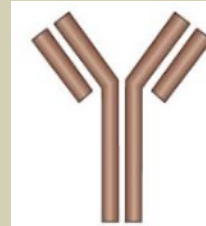
Ustekinumab



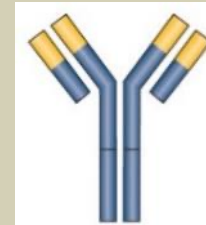
Adalimumab



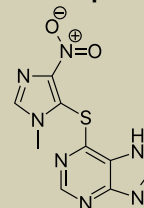
Vedolizumab



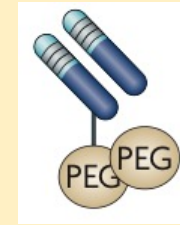
Infliximab



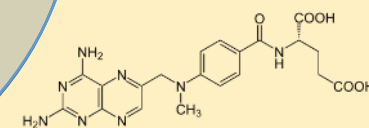
Azathioprine



Certolizumab



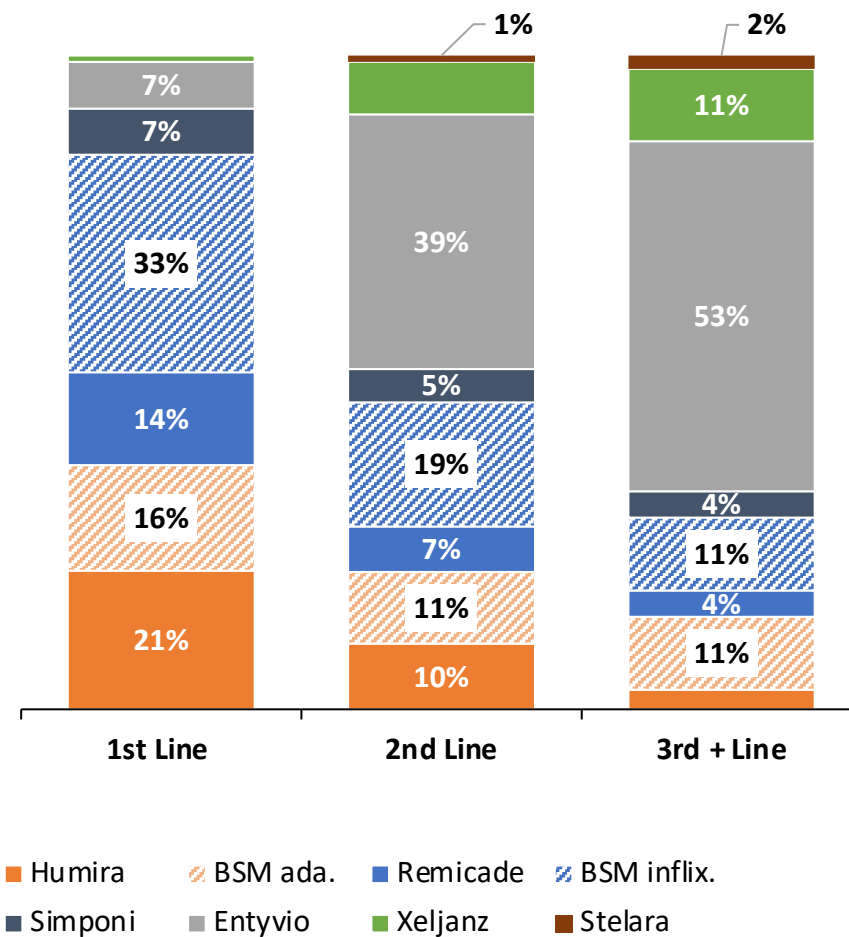
Methotrexate



## EU5: TNFs remain most frequently used in early lines of treatment

### UC Patient Share by Line of Therapy in EU5

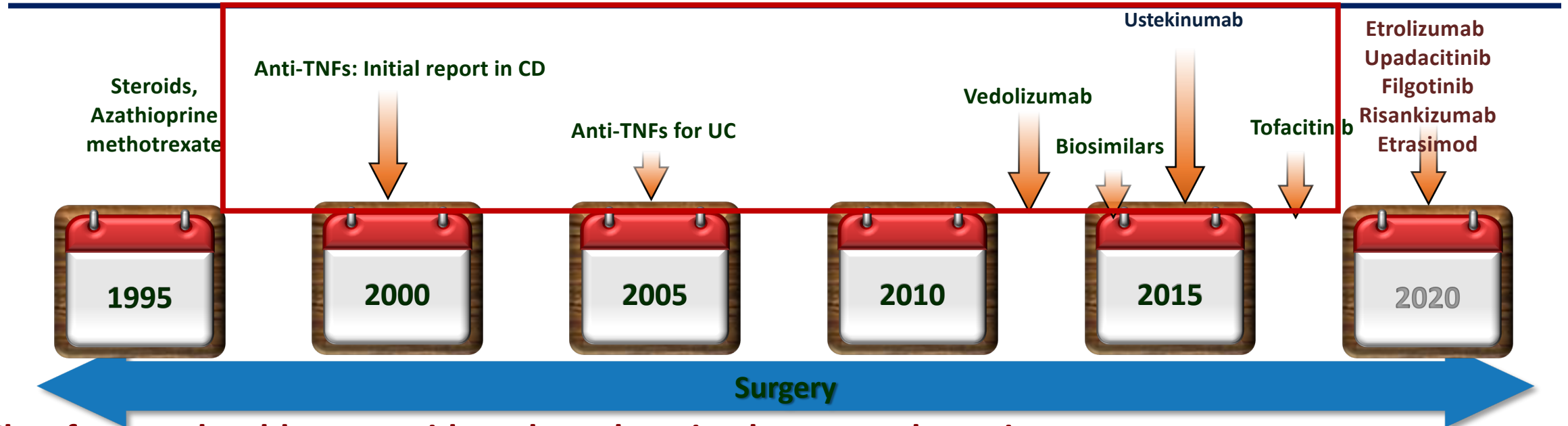
% share by line of therapy, Q2 2020





# Breaking through the glass ceiling of biologics efficacy

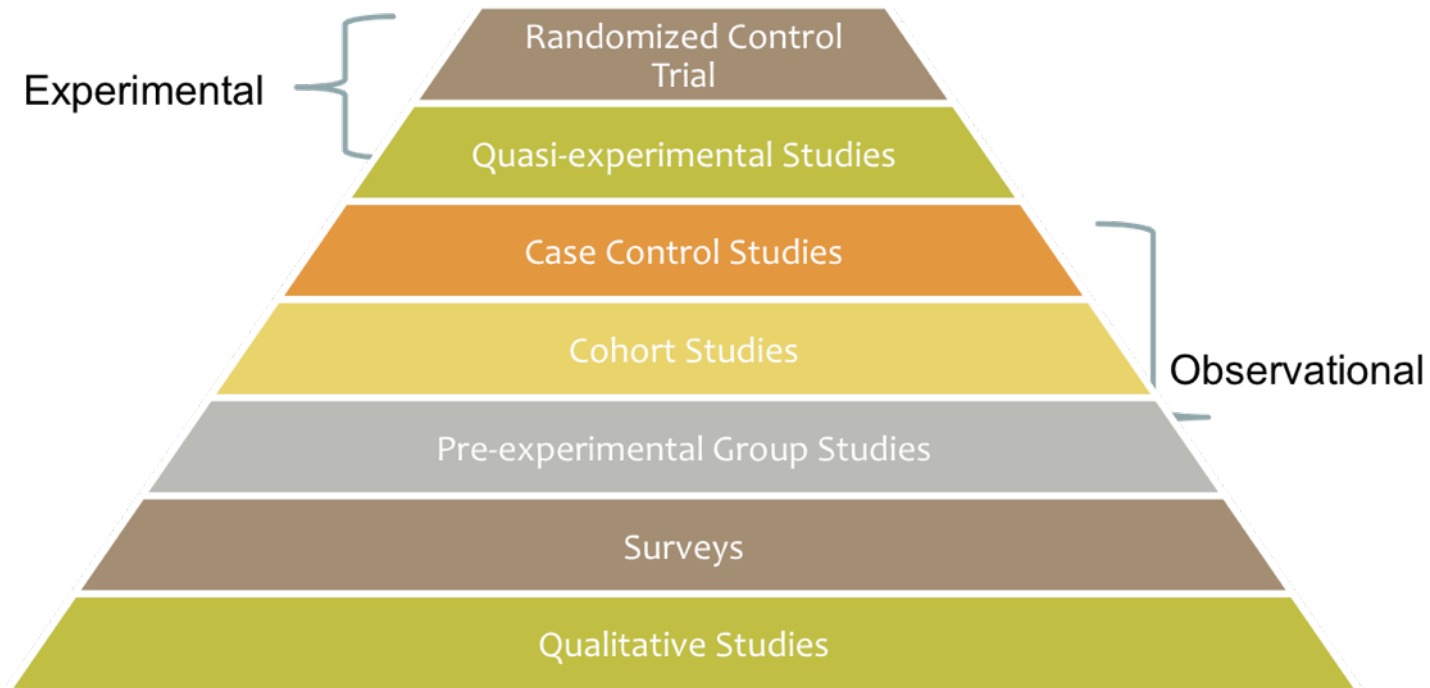
*The choice of drugs is increasing*



## What factors should we consider when choosing between therapies

- Which drugs are effective – all the above agents show efficacy in phase III clinical trials
- *Which drug is more effective?*
  - *And does effective mean?*
- Which drug will be effective in this patient
- What risks will the patient be exposed to with this drug?

# Hierarchies of evidence



# How do we compare the therapeutic benefit between agents

*Important to understand that the endpoint definitions vary between studies*

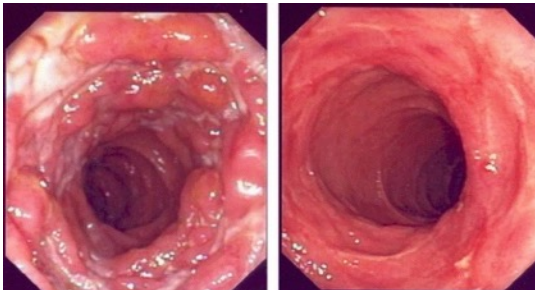
Symptomatic  
benefit



Steroid-free  
remission



PRO / Mucosal  
healing



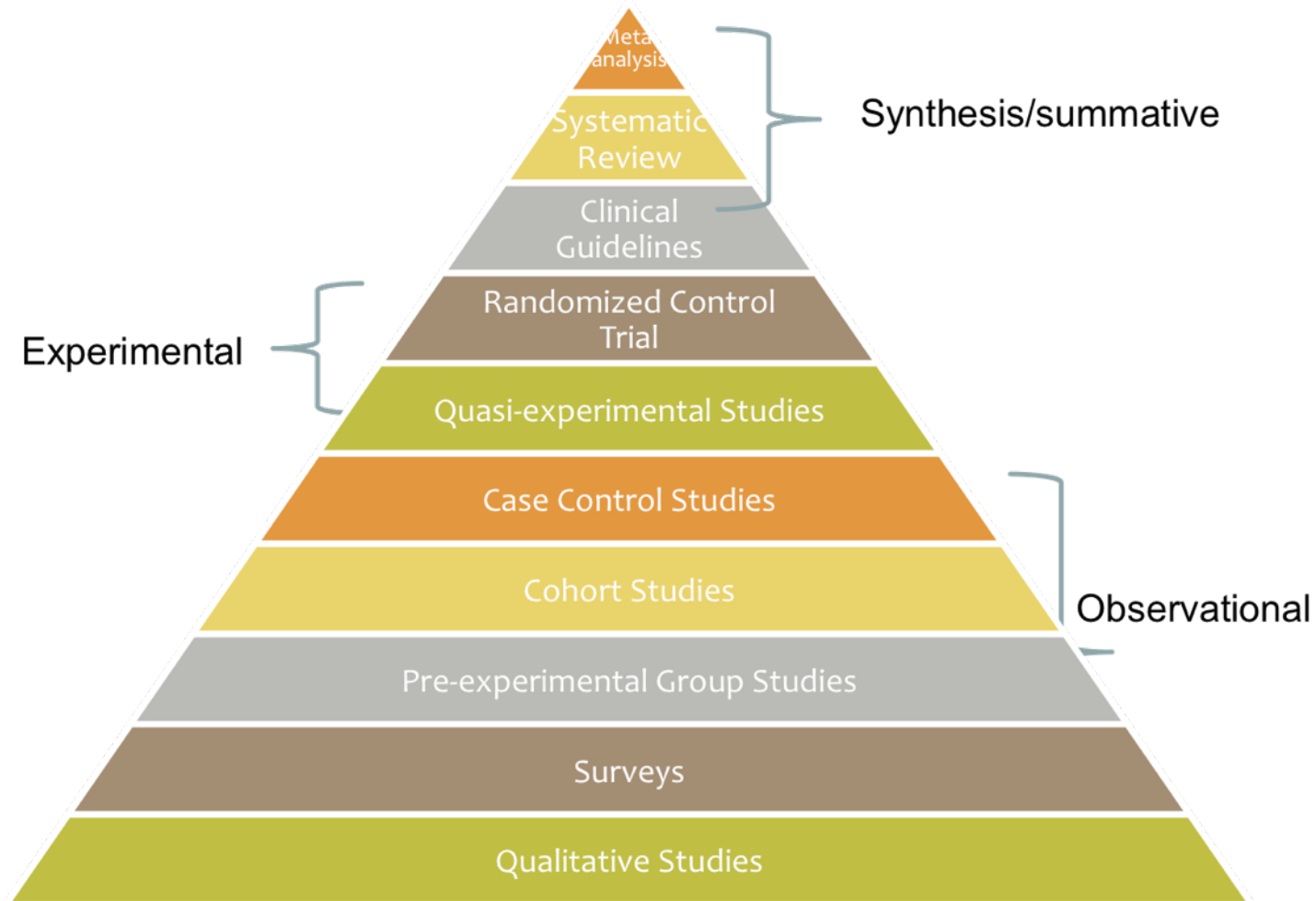
Histological  
remission



Prevent  
hospitalisation  
and surgery

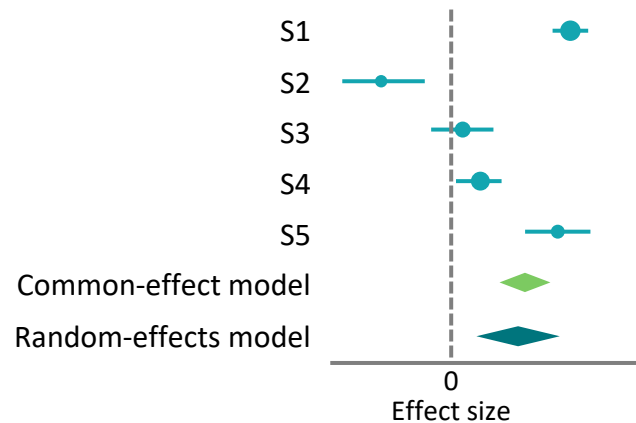
*There is also heterogeneity for each endpoint*

# New hierarchies of evidence



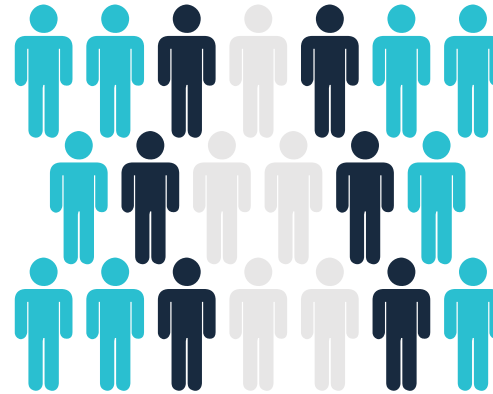
# What Tools Do We Have to Compare Therapeutic Options?

## Meta-analysis<sup>1</sup>



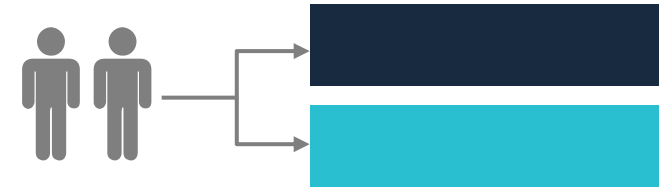
Integrates findings from many individual studies (often RCTs), applying objective statistical formulas

## Real-world data<sup>2</sup>



Routinely collects data on patient health status from many sources (eg, registries), often using propensity score-matched analysis for adequate comparisons

## Head-to-head trial<sup>3,4</sup>



Gold standard: Designed and powered to allow formal comparison between different active therapies

*RCTs, randomised controlled trials.*

1. Gurevitch J, et al. *Nature*. 2018;555:175-82. 2. Corrigan-Curay J, et al. *JAMA*. 2018;320:867-8. 3. Peyrin-Biroulet L, et al. *J Crohns Colitis*. 2017;S567-75.

4. Favalli E, et al. *BioMed Res Int*. 2014;2014:831603.

Please vote

In your routine practice, what set of studies most influences your drug selection for advanced therapies in UC?



1 Head to head RCT



2 Network meta-analyses



3 Propensity score matching studies



4 None – I don't believe any of them!



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