



# Update on the MesaCapp Study

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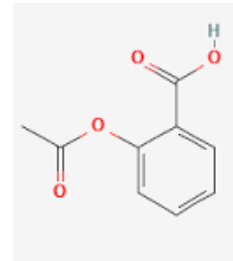




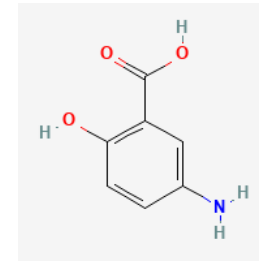
## Mesalazine (5-ASA) instead of ASA

- Mesalazine is used to treat mild to moderate ulcerative colitis.
- Anti-inflammatory
- In 2007, Mesalazine was associated with colorectal cancer reduction in patients with ulcerative colitis

Aspirin



Mesalazine



## Rationale

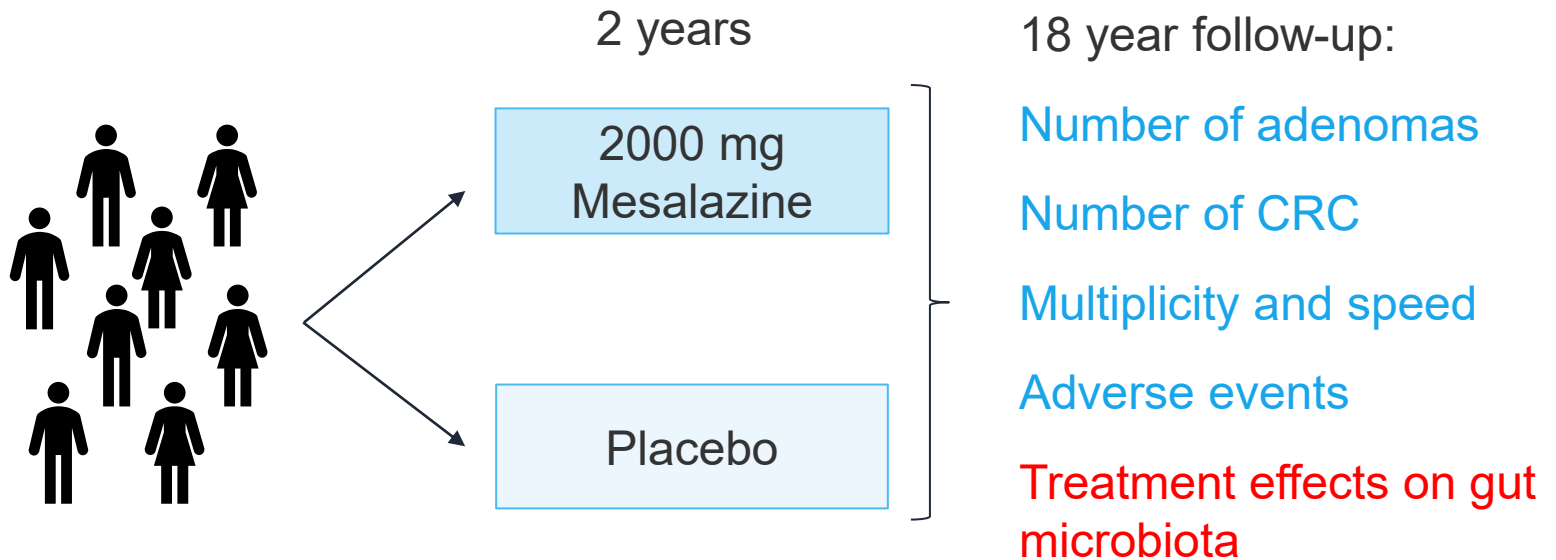
- Aspirin and Mesalazine share biologic similarities
  - Same biologic effect on the COX2 inhibition and inflammation
- Mesalazine has some advantages
  - Additional effects on apoptosis, and lower the production of ROS and frameshift mutations in microsatellites
- Mesalazine has local effect
  - Less side effects than Aspirin



## MesaCAPP – like CAPP2



Ann-Sofie Backman, PhD and MD  
Karolinska Institute, Stockholm, Sweden  
Funding from the Swedish Research Council  
Sponsored by Ferring (donate Mesalazine and placebo)



**Expected to find a 50% reduction in the development of adenoma/CRC**

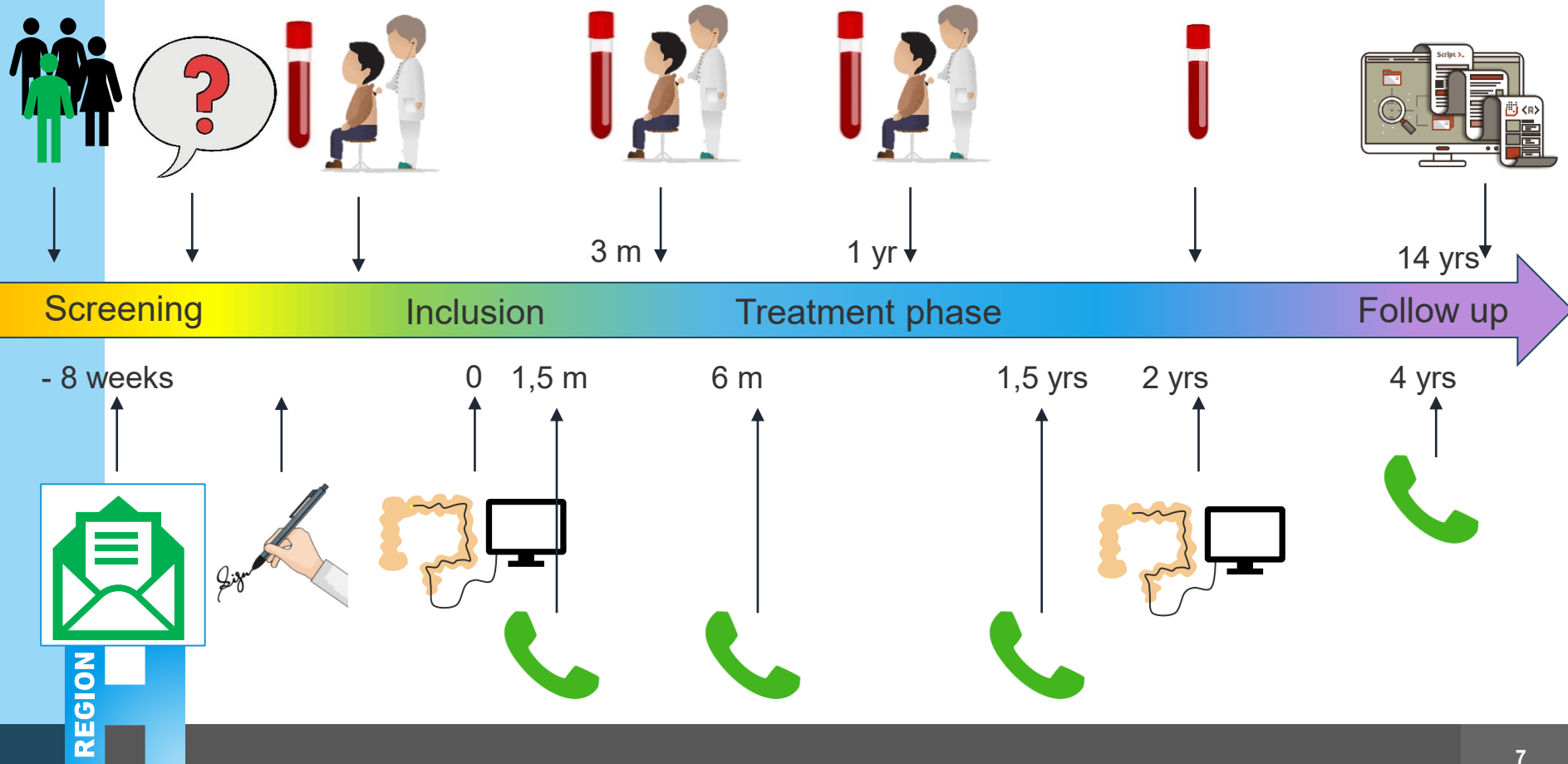


# Flow chart

2022-2025

2022-2027

2024-2045



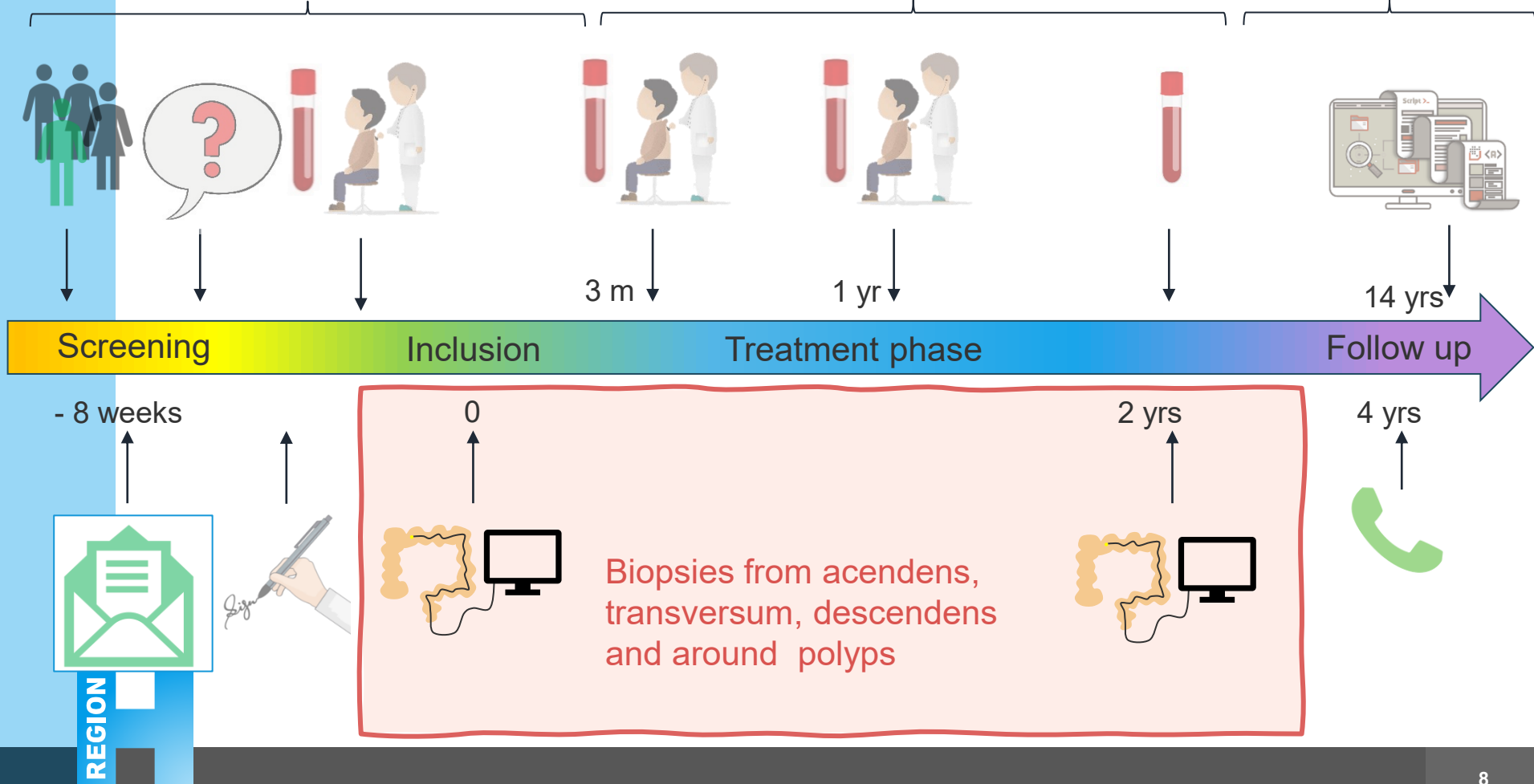


# Flow chart

2022-2025

2022-2027

2024-2045





# Sites: Sweden and Denmark



Gothenburg 2022

Aalborg 2024

Copenhagen 2022



Umeå 2023

Uppsala 2024

Stockholm Karolinska 2022  
and Ersta hospital 2024

Malmö 2023



AKADEMISKA  
SJUKHUSET



Karolinska  
Institutet

KAROLINSKA  
UNIVERSITETSSJUKHUSET

Karolinska Comprehensive Cancer Center



ERSTA  
SJUKHUS

SAHLGRENKA  
UNIVERSITETSSJUKHUSET



AALBORG UNIVERSITY  
DENMARK



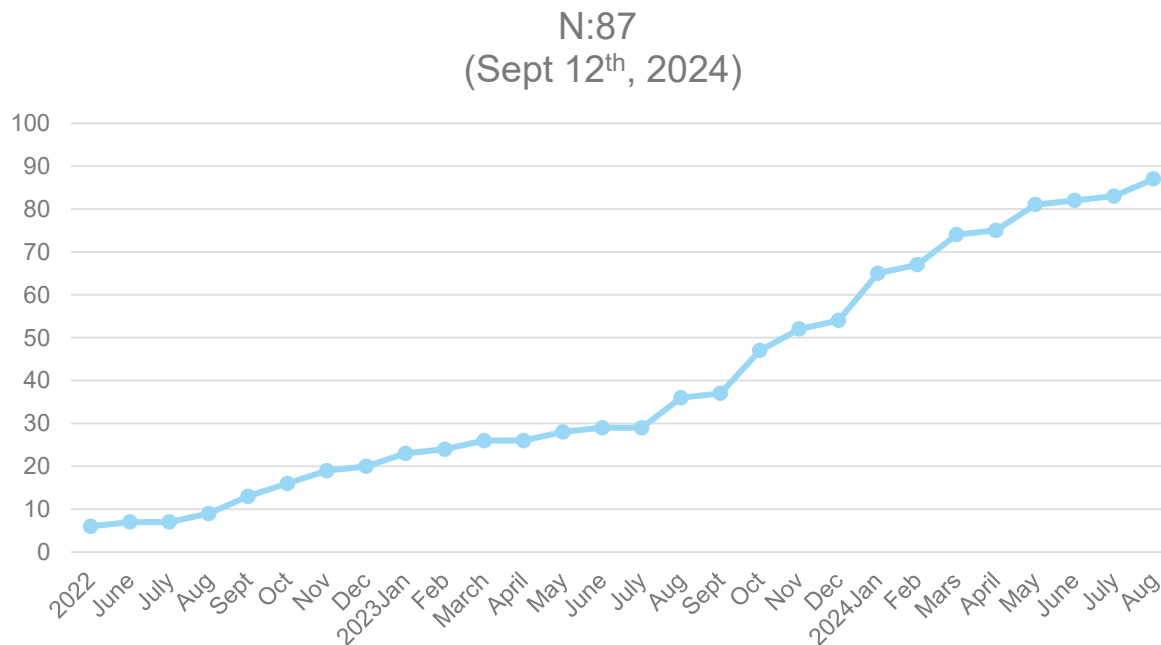
Hvidovre  
Hospital

REGION





## Inclusion - Intention to treat 2022-2024



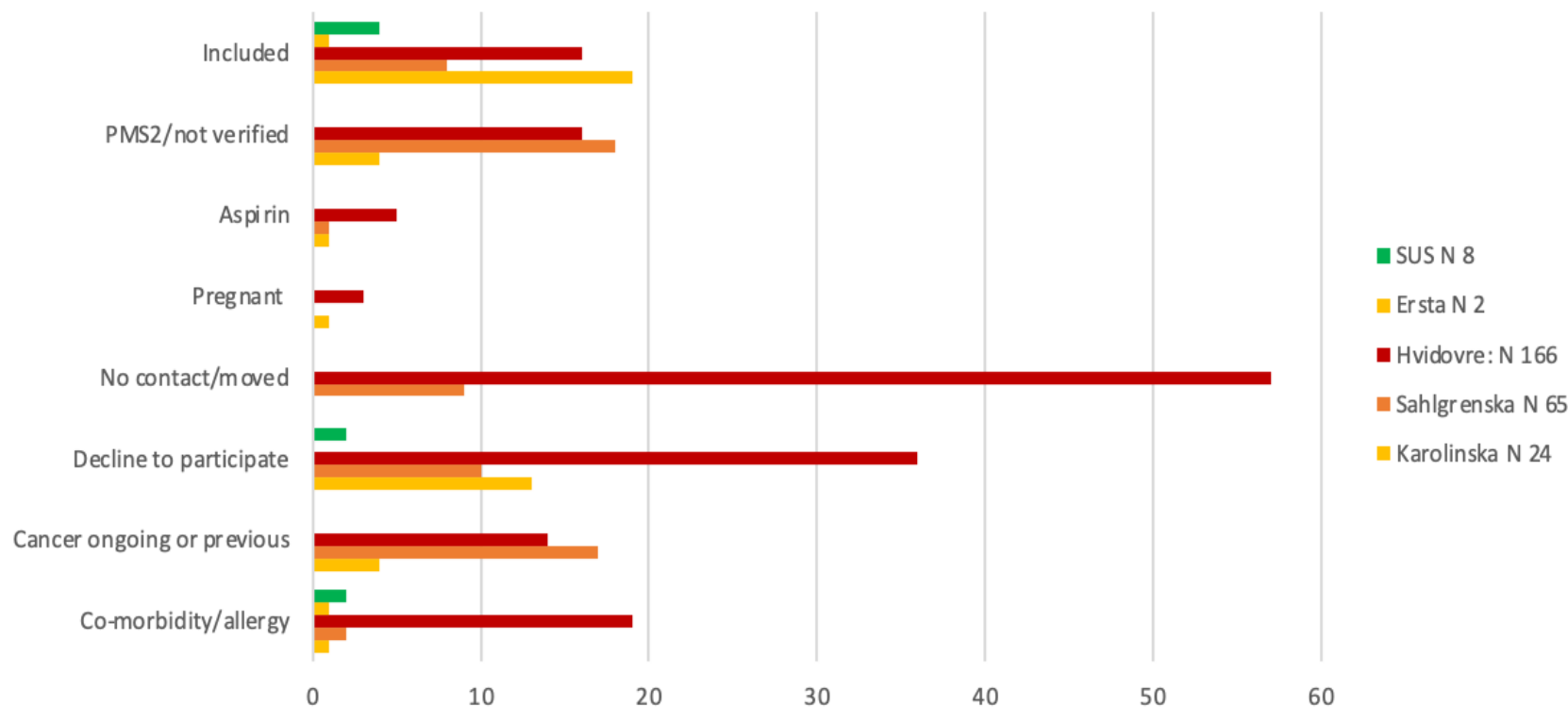
| Country | Site                            | Included patients |
|---------|---------------------------------|-------------------|
| Denmark | Hvidovre Hospital               | 42                |
| Sweden  | Karolinska University Hospital  | 21                |
|         | Sahlgrenska University Hospital | 11                |
|         | Skåne University Hospital       | 4                 |
|         | Norrlands University Hospital   | 4                 |
|         | Ersta sjukhus                   | 4                 |

No adverse effects were observed so far



# Inclusion – Screening log

MesaCapp Screeninglog 2022-2023





# Study population

| Study population                     |         | N 87     | Min-max(mean) | Median |
|--------------------------------------|---------|----------|---------------|--------|
| Sex                                  | Male    | 45(52%)  |               |        |
|                                      | Female  | 42(48%)  |               |        |
| Genotype                             | MLH1    | 27(31%)  |               |        |
|                                      | MSH2    | 29(34%)  |               |        |
|                                      | MSH6    | 28(33%)  |               |        |
|                                      | Missing | 2 (2%)   |               |        |
| Age (years)                          |         |          | 30-75(48)     | 48     |
| Previous history of stage 1 or 2 CRC | Yes     | 5 (6%)   |               |        |
|                                      | No      | 79 (92%) |               |        |
|                                      | Missing | 3 (2%)   |               |        |



## Amendment – Slow inclusion

- Sponsor moved from Karolinska University Hospital to Karolinska University
- Aalborg Hospital is a new inclusion site in DK
- Study inclusion prolonged to 2025 (treatment to 2027)
- The aim to investigate the difference between 5-ASA and placebo is now a descriptive objective -> numbers needed to be included reduced from 260 to 150
- Number needed to screen increased from 600 to 1000



## Amentment – New aims

- Added aim to investigate metabolic, inflammatory, and genetic biomarkers associated with Lynch syndrome and 5-ASA treatment
- To investigate the effect of 5-ASA on the microbiome during treatment
- To investigate the effect of 5-ASA on the immunological profile of the colon epithelium during treatment



## Amendment – More samples

- Changes in the aims require collection of new samples
  - Blood measures (fasting glucose and cholesterol)
  - Urine samples
  - Additional biopsies (microbiome, inflammatory/immunological colon profile)



