



# Participant Baseline Questionnaire

## (v9-0 22Mar2012)

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### CONSTRUCT

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Thank you for agreeing to participate in this study. The answers you give for this questionnaire will help us to find out whether the treatments you receive are helpful for your condition.

The information you provide will be completely confidential and will not be accessible by any third parties.

**Please answer all the questions.** Although it may seem that some questions are asked more than once, it is still important that you answer every one.

If you find it difficult to answer a question, please do the best you can. If you are unsure what the question is asking, please ask the research nurse to explain it.

Please follow the instructions for each section of the questionnaire carefully as the sections ask you to think back about different periods of time.

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Date questionnaire started: 

<i>d</i>	<i>d</i>	<i>m</i>	<i>m</i>	<i>y</i>	<i>y</i>	<i>y</i>	<i>y</i>
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Time questionnaire started: 

<i>h</i>	<i>h</i>	<i>m</i>	<i>m</i>
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 (*using 24h clock*)

Date questionnaire completed: 

<i>d</i>	<i>d</i>	<i>m</i>	<i>m</i>	<i>y</i>	<i>y</i>	<i>y</i>	<i>y</i>
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Time questionnaire completed: 

<i>h</i>	<i>h</i>	<i>m</i>	<i>m</i>
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 (*using 24h clock*)

Patient initials: 

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***For completion by the researcher only***

Name of researcher completing this questionnaire: \_\_\_\_\_

Has the patient completed the questionnaire without you being present?

- |  |             |
|--|-------------|
|  | Yes in full |
|  | Yes in part |
|  | No          |

## Section A: Crohn's and Colitis Questionnaire (CCQ)

The following questions ask for your views about your bowel problem and how it has affected your life over the **last two weeks**.

Please answer **all the questions**. If you are unsure about how to answer any question, just give the best answer you can. Do not spend too much time answering, as your first thoughts are likely to be the most accurate.

If you **do not wish to answer a question**, please leave it blank and complete **page 9** with details of the question and reason(s) why it was not answered.

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1. On how many days over the last **two weeks** have you had loose or runny bowel movements?

 days

2. On how many days in the last **two weeks** have you noticed blood in your stools?

 days

3. On how many days over the last **two weeks** have you felt tired?

 days

4. In the last **two weeks** have you felt frustrated?

- a) No, not at all
- b) Yes, some of the time
- c) Yes, most of the time
- d) Yes, all of the time

5. In the last **two weeks**, has your bowel condition prevented you from carrying out your work or other normal activities?

- a) No, not at all
- b) Yes, some of the time
- c) Yes, most of the time
- d) Yes, all of the time

6. On how many days over the last **two weeks** have you opened your bowels more than three times a day?

 days

7. On how many days over the last **two weeks** have you felt full of energy?

 days

8. In the last **two weeks** did your bowel condition prevent you from going out socially?

- a) No, not at all
- b) Yes, some of the time
- c) Yes, most of the time
- d) Yes, all of the time

9. On how many days over the last **two weeks** have your bowels opened accidentally?

 days

10. On how many days over the last **two weeks** have you felt generally unwell?

 days

11. In the last **two weeks** have you felt the need to keep close to a toilet?

- a) No, not at all
- b) Yes, some of the time
- c) Yes, most of the time
- d) Yes, all of the time

12. In the last **two weeks**, has your bowel condition affected your leisure or sports activities?

- a) No, not at all
- b) Yes, some of the time
- c) Yes, most of the time
- d) Yes, all of the time

13. On how many days over the last **two weeks** have you felt pain in your abdomen?

days

14. On how many nights over the last **two weeks** have you been unable to sleep well (days if you are a shift worker)?

nights (or days)

15. On how many nights in the last **two weeks** have you had to get up to use the toilet because of your bowel condition after you have gone to bed?

nights

16. In the last **two weeks** have you felt depressed?

- a) No, not at all
- b) Yes, some of the time
- c) Yes, most of the time
- d) Yes, all of the time

17. In the last **two weeks** have you had to avoid attending events where there was no toilet close at hand?

- a) No, not at all
- b) Yes, some of the time
- c) Yes, most of the time
- d) Yes, all of the time

18. On how many days over the last **two weeks**, have you had a problem with large amounts of wind?

days

19. On how many days over the last **two weeks** have you felt off your food?

days

20. Many patients with bowel problems have worries about their illness. How often during the last **two weeks** have you felt worried?

- a) No, not at all
- b) Yes, some of the time
- c) Yes, most of the time
- d) Yes, all of the time

21. On how many days over the last **two weeks** has your abdomen felt bloated?

days

22. In the last **two weeks** have you felt relaxed?

- a) No, not at all
- b) Yes, some of the time
- c) Yes, most of the time
- d) Yes, all of the time

23. In the last **two weeks** have you been embarrassed by your bowel problem?

- a) No, not at all
- b) Yes, some of the time
- c) Yes, most of the time
- d) Yes, all of the time

24. On how many days over the last **two weeks** have you wanted to go back to the toilet immediately after you thought you had emptied your bowels?

days

25. In the last **two weeks** have you felt upset?

- a) No, not at all
- b) Yes, some of the time

- c) Yes, most of the time
- d) Yes, all of the time

26. On how many days over the last **two weeks** have you had to rush to the toilet?

days

27. In the last **two weeks** have you felt angry as a result of your bowel problem?

- a) No, not at all
- b) Yes, some of the time
- c) Yes, most of the time
- d) Yes, all of the time

28. In the last **two weeks**, has your sex life been affected by your bowel problem?

- a) No, not at all
- b) Yes, some of the time
- c) Yes, most of the time
- d) Yes, all of the time

29. On how many days over the last **two weeks** have you felt sick?

days

30. In the last **two weeks** have you felt irritable?

- a) No, not at all
- b) Yes, some of the time
- c) Yes, most of the time
- d) Yes, all of the time

31. In the last **two weeks** have you felt lack of sympathy from others?

- a) No, not at all
- b) Yes, some of the time
- c) Yes, most of the time
- d) Yes, all of the time

32. In the last **two weeks** have you felt happy?

- a) No, not at all
- b) Yes, some of the time
- c) Yes, most of the time
- d) Yes, all of the time

If you did not complete any of these questions, please record the question number(s) below and, if possible, give a reason why it was not completed.

Question N°	Reason for non-completion

### ***Section B: 3 month Health Status***

Please circle which one of the five statements below best describes the effect of your bowel condition over the last **three months**?

- |                           |                            |                                  |                          |                         |
|---------------------------|----------------------------|----------------------------------|--------------------------|-------------------------|
| <b>1</b>                  | <b>2</b>                   | <b>3</b>                         | <b>4</b>                 | <b>5</b>                |
| Unwell all<br>of the time | Unwell most<br>of the time | Unwell about<br>half of the time | Well most of<br>the time | Well all of<br>the time |



## Section C: SF-12

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

For each of the following questions, please tick the **one box** that best describes your answer.

1. **In general**, would you say your health is:

<b>Excellent</b>	<b>Very good</b>	<b>Good</b>	<b>Fair</b>	<b>Poor</b>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

	<b>Yes, limited a lot</b>	<b>Yes, limited a little</b>	<b>No, not limited at all</b>
a) <u>Moderate activities</u> , such as moving a table, pushing a vacuum cleaner, or playing golf	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Climbing <u>several</u> flights of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. During the past **4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

	<b>All of the time</b>	<b>Most of the time</b>	<b>Some of the time</b>	<b>A little of the time</b>	<b>None of the time</b>
a) <u>Accomplished less</u> than you would like	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Were limited in the <u>kind of work or other</u> Activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. During the past **4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

	<b>All of the time</b>	<b>Most of the time</b>	<b>Some of the time</b>	<b>A little of the time</b>	<b>None of the time</b>
a) <u>Accomplished less</u> than you would like	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Did work or other activities <u>less carefully</u> than usual	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5. During the past **4 weeks**, how much did pain interfere with your normal work (including both work outside the home and housework)?

**Not at all**

**A little bit**

**Moderately**

**Quite a bit**

**Extremely**

6. These questions are about how you feel and how things have been with you during the past **4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past **4 weeks**...

**All of  
the time**

**Most of  
the time**

**Some of  
the time**

**A little of  
the time**

**None of  
the time**

a) Have you felt calm and peaceful?

b) Did you have lots of energy?

c) Have you felt downhearted and low?

7. During the past **4 weeks**, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

**All of  
the time**

**Most of  
the time**

**Some of  
the time**

**A little of  
the time**

**None of  
the time**

## Section D: EQ-5D

By placing a tick in one box in each group below, please indicate which statements best describe your own health state **today**.

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### Mobility

- I have no problems in walking about  A
- I have some problems in walking about  B
- I am confined to bed  C

### Self-Care

- I have no problems with self-care  A
- I have some problems washing or dressing myself  B
- I am unable to wash or dress myself  C

### Usual Activities (e.g. work, study, housework, family or leisure activities)

- I have no problems with performing my usual activities  A
- I have some problems with performing my usual activities  B
- I am unable to perform my usual activities  C

### Pain/Discomfort

- I have no pain or discomfort  A
- I have moderate pain or discomfort  B
- I have extreme pain or discomfort  C

### Anxiety/Depression

- I am not anxious or depressed  A
- I am moderately anxious or depressed  B
- I am extremely anxious or depressed  C

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

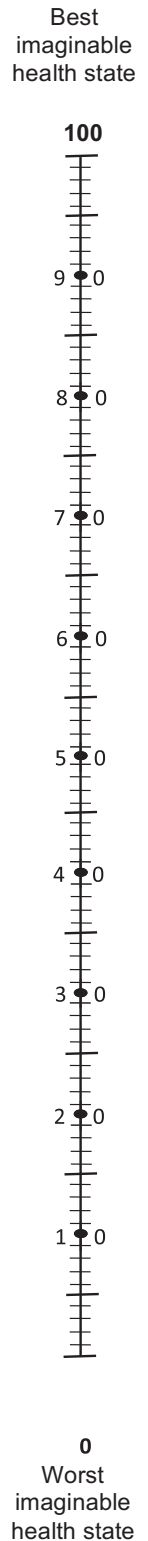
We would like you to indicate on this scale how good or bad your own health is today, in your opinion.

Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

**Your own  
health state  
today**

**Office use only:**

Health state indicated (*whole number between 0 and 100*).



## Section E: Resource use questionnaire

This section is about the health care you have received – **apart from any services at the hospital where you were recruited.**

All questions refer to the **three months before your admission for this episode.**

We would like to know about contacts you have had with health professionals in the last three months **for any reason - not just with regard to your bowel condition.**

Please ensure that if you tick "Yes", that you also enter the number of times alongside the corresponding healthcare professional. Where there is no number written in a box, we will assume that the answer is zero.

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1. In the last **3 months**, have you been seen for any reason by any of the following **at your GP surgery?**

- *Your own or another GP*
- *Nurse*
- *Any other health professional (e.g. dietician, physiotherapist, health visitor)*

No

**Please go to Question 2**

Yes

Please enter the number of times for...

- Your own or another GP
- Nurse
- Other (please specify)


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2. In the last **3 months**, have you been seen for any reason by any of the following **at home?**

- *Your own or another GP*
- *Nurse*
- *Any other health professional (e.g. dietician, physiotherapist, health visitor)*

No

**Please go to Question 3**

Yes

Please enter the number of times for...

- Your own or another GP
- Nurse
- Other (please specify)


3. In the last **3 months**, have you had a **telephone** discussion with any of the following **about any health issue** (NOT just to make or change appointments)?

- *With anyone at your GP surgery*
- *With anyone at any hospital*
- *With NHS Direct (NHS 24 if in Scotland)*
- *With a health professional at another location*

No

**Please go to Question 4**

Yes

Please enter the number of times....

- *With anyone at your GP surgery*
- *With anyone at any hospital*
- *With NHS Direct / NHS 24*
- *With a health professional at another location*


*(Please specify)* \_\_\_\_\_

4. In the last **3 months**, have you visited an accident and emergency (A&E) department **other than** at the hospital where you were recruited to the study?

No

**Please go to Question 5**

Yes

Please enter the number of times you visited another A&E

5. In the last **3 months**, have you been admitted as an in-patient (i.e. stayed overnight in hospital) for any reason at a hospital **other than** at the hospital where you were recruited to the study?

No

**Please go to Question 6**

Yes

Please enter the number of **nights** you spent in hospital

6. If **you are in work**, did you take any time off work *either* due to illness or in order to see any health professional, for any reason, in the last **3 months**? *If you do not work, select "No".*

No

**Please go to Section F**

Yes

Please enter the number of day (to the nearest **half day**)

## Section F: Drugs use questionnaire

Section F concerns **ONLY** prescribed drugs taken regularly in the three months prior to the admission.

Please do **NOT** include any of the following

- 1) drugs purchased without a prescription,
- 2) drugs given as an inpatient at the study centre during the admission
- 3) drugs which were prescribed to be taken on an "as required" basis.

Please give details of how each drug was **INTENDED** to be taken (i.e. the prescription details), rather than how it **WAS** taken.

Have you been given a **prescription** for any of the following drugs in the last **three months**? *If so, please record the strength of each tablet, the number to be taken per dose and the dose frequency. If the course was less than 3 months, please record the number of days it was prescribed for.*

### Drugs for colitis (listed in alphabetical order)

Name of Drug	Strength of each tablet	Number taken per dose	Dose frequency	Duration (days) if short course
Asacol MR	_____	_____	_____	_____
Azathioprine	_____	_____	_____	_____
Budenofalk	_____	_____	_____	_____
Codeine phosphate	_____	_____	_____	_____
Colazide	_____	_____	_____	_____
Dipentum	_____	_____	_____	_____
Entocort	_____	_____	_____	_____

*Continued overleaf*

Name of Drug	Strength of each tablet	Number taken per dose	Dose frequency	Duration (days) if short course
Imodium	_____	_____	_____	
Lomotil	_____	_____	_____	
Mercaptopurine	_____	_____	_____	
Mesavant XL	_____	_____	_____	
Methotrexate	_____	_____	_____	
Pentasa	_____	_____	_____	
Prednisolone by mouth*	_____	_____	_____	
Salazopyrin	_____	_____	_____	
Salofalk	_____	_____	_____	
Tacrolimus	_____	_____	_____	

\*For oral prednisolone with reducing dose, please provide details below.




## Suppositories for colitis

Have you been given a prescription for any of the following suppositories in the last **three months**? If so, please record the strength of each tablet, the number to be taken per dose and the dose frequency. If the course was less than 3 months, please record the number of days it was prescribed for.

Name of Suppository	Strength	Number taken per dose	Dose frequency	Duration (days) if short course
Asacol	_____	_____	_____	_____
Pentasa	_____	_____	_____	_____
Salofalk	_____	_____	_____	_____
Predsol	_____	_____	_____	_____

## Enemas for colitis

Have you been given a prescription for any of the following **prescribed** enemas in the last **three months**? If so, please state how many you were prescribed.

Asacol \_\_\_\_\_

Colifoam \_\_\_\_\_

Pentasa \_\_\_\_\_

Predenema \_\_\_\_\_

Predfoam \_\_\_\_\_

Predsol \_\_\_\_\_

Salofalk \_\_\_\_\_

## **Medication for general GI disorders**

Have you been given a prescription for any of the following **prescribed** drugs in the last **three months**?

*If so, please record the strength of each tablet, the number to be taken per dose and the dose frequency.*

*If the course was less than 3 months, please record the number of days it was prescribed for.*

<b>Name of Drug</b>	<b>Strength of each tablet</b>	<b>Number to be taken per dose</b>	<b>Dose frequency</b>	<b>Duration (days) if short course</b>
<b>Axid</b> (Nizatidine)	_____	_____	_____	_____
<b>Buscopan</b> (Hyoscine)	_____	_____	_____	_____
<b>Colofac</b> (Mebeverine)	_____	_____	_____	_____
<b>Colpermin</b> (Peppermint oil)	_____	_____	_____	_____
<b>Fybogel</b> (Ispaghula husk)	_____	_____	_____	_____
<b>Maxolon</b> (Metoclopramide)	_____	_____	_____	_____
<b>Merbentyl</b> (Dicycloverine)	_____	_____	_____	_____
<b>Motilium</b> (Domperidone)	_____	_____	_____	_____
<b>Nexium</b> (Esomeprazole)	_____	_____	_____	_____
<b>Losec</b> (Omeprazole)	_____	_____	_____	_____
<b>Pariet</b> (Rabeprazole)	_____	_____	_____	_____
<b>Pepcid</b> (Famotodine)	_____	_____	_____	_____
<b>Protium</b> (Pantoprazole)	_____	_____	_____	_____
<b>Questran</b> (Colestyramine)	_____	_____	_____	_____
<b>Spasmonal</b> (Alverine)	_____	_____	_____	_____
<b>Tagamet</b> (Cimetidine)	_____	_____	_____	_____
<b>Zantac</b> (Ranitidine)	_____	_____	_____	_____
<b>Zoton</b> (Lansoprazole)	_____	_____	_____	_____

## Medication not listed

Have you been **given a prescription** for any other drugs in the **three months** prior to your admission that have not been listed here such as antibiotics or drugs for any health condition, not just your bowel condition.

If so, please enter the details of the drug(s) in the table below.

REMEMBER - do not include:

- 1) any drugs purchased without prescription
- 2) drugs which were prescribed to be taken on an "as required" basis.

Please give details of how each drug was **INTENDED** to be taken (i.e. the prescription details), rather than how it WAS taken.

Drug Name	Strength of each tablet	N° taken per dose	Dose frequency	Duration (days) if short course
<i>e.g. amoxicillin</i>	<i>500mg</i>	<i>1</i>	<i>3 times a day</i>	<i>7 days</i>

Please record any additional drugs or comments on the blank page overleaf.