Patient Study Number: _____

Date of consultation: Day____Month_____Year____

ARTIC PC

Diagnosis & treatment study
Diary

Version 1 (09.08.16)

INSTRUCTIONS

Your doctor or nurse and researchers from the **ARTIC-PC** study would like to thank you for your kind and important contribution to this research. We wish your child a speedy recovery!

What is the ARTIC-PC study?
The purpose of this study is to improve our understanding of how to treat coughs/chest infections in children.

What do I need to do?
We would like you do complete a few questions about your child and their health. There are 3 different sections which we would like you to complete. You complete it on behalf of your child and from the child's perspective, but with the child's help wherever possible, particularly for older children. **NB** if your child is under 4 years old you do not need to answer the questions 'Describing your child's health today'.

- **SECTION A - General Questions**. Please answer these questions **today** (the day your child was seen by the GP/nurse). This should take no more than 5 minutes.

- **SECTION B - Daily Symptom Diary**. Please start **today** (the day your child was seen by your GP or nurse) and complete it every day until you score '0' for all symptoms.

    - **Weekly Questions**. At the end of each week there are questions. This should take you less than five minutes each week. If your child has NOT had any symptoms for an entire week then you do not need to do another weekly diary.

- **SECTION C - Final Questionnaire**. Please answer these questions when your child either has no more symptoms, or it is day 28. This should take no more than 5 minutes. You have now completed the diary.

What do I do when I've completed all 3 sections?
You should have a follow up appointment with the practice nurse please bring this diary and any unused medication with you for that appointment.

What should I do if I have questions or problems filling in or returning this diary?
If you have any problems or questions about the diary, or if you have lost the return envelope, or if you have questions about this research study, please contact us at *[name University/organisation NNC]*

SECTION A – General Questions

Please answer as soon as possible after seeing your GP or nurse:

1. What is the child's mothers age (years) _____

Please tell us about your child

2. What is their date of birth? ☐☐ ☐☐ ☐☐☐☐

3. Are they: Boy ☐ Girl ☐

4. Was the child still breast fed at 3 months?

   No ☐ Yes ☐ Don't know ☐

5. Does he/she have any long-term illness, health problem, or illness/disease which limits his/her daily activities?

   No ☐ Yes ☐

   If **Yes**, please give details below,

   _____

   _____

6. Has he/she ever had hay fever or eczema?

   No ☐ Yes ☐

7. Has any person in their family (parents, grandparents, sisters, brothers) had asthma?

   No ☐ Yes ☐ Don't know ☐

8. How many times have they had a cough lasting more than a week in the last 12 months?

   _____

9. Other than with the cough / chest infection he/she has at the moment, has he/she in the last 12 months…

		Yes	No	Unknown
a)	Had wheezing or whistling in their chest?			
b)	Woken up with a feeling of tightness in their chest?			
c)	Been woken up by an attack of coughing?			

Please tick Yes, No or Unknown for all 3 questions above.

Questions about your child's cough / chest infection

10. Did you contact the surgery about your child's cough/chest infection for advice before this visit?

    No ☐ Yes ☐

11. Did you visit the surgery with your child for this illness before today's appointment?

    No ☐ Yes ☐

12. How many days was your child unwell for before you saw your GP or nurse for ***this*** illness? _____days

13. Did you treat this illness with any over the counter medications before going to your GP?

    No ☐ Yes ☐

    If yes, please give the details of what you gave him/her:

Medication:	***Please tick if yes***	**How often taken:**	**Average dose taken**	**Prescription? *Please Circle***
Paracetamol				**Yes No**
Ibuprofen				**Yes No**
Other pain medication				**Yes No**
Vitamins				**Yes No**
Inhaled medication				**Yes No**
Cough medicine				**Yes No**
Lozenges / Mouth washes / gargles				**Yes No**
Nose spray				**Yes No**
Ear drops				**Yes No**
Herbal/ Complementary medicines				**Yes No**

14. Have you given your child any other remedies for this illness before going to your GP?

    No ☐ Yes ☐

    If yes, please give the details of what you gave him/her:

Name of remedy:	**Number of days they took the remedy?**	**Average dose taken?**

Describing your child's health TODAY

Under each heading, please tick the ONE box that best describes your health TODAY.

Mobility *(walking about)*

I have no problems walking about ❑

I have some problems walking about ❑

I have a lot of problems walking about ❑

Looking after myself

I have no problems washing or dressing myself ❑

I have some problems washing or dressing myself ❑

I have a lot of problems washing or dressing myself ❑

Doing usual activities *(for example, going to school, hobbies, sports, playing, doing things with family or friends)*

I have no problems doing my usual activities ❑

I have some problems doing my usual activities ❑

I have a lot of problems doing my usual activities ❑

Having pain or discomfort

I have no pain or discomfort ❑

I have some pain or discomfort ❑

I have a lot of pain or discomfort ❑

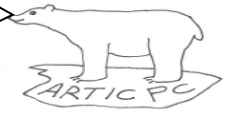
Feeling worried, sad or unhappy

I am not worried, sad or unhappy ❑

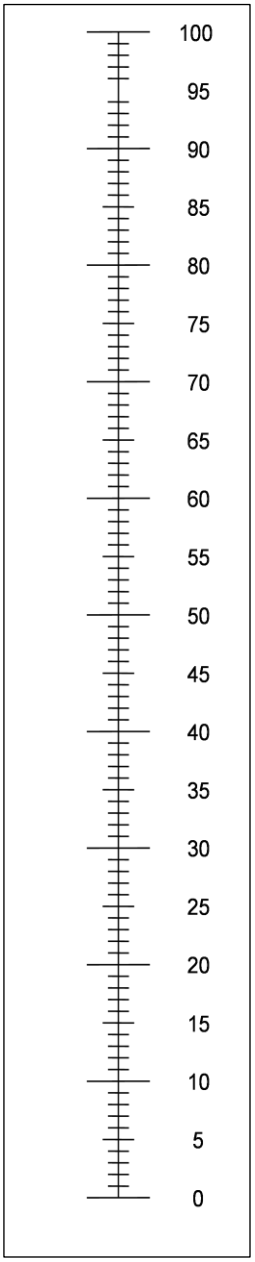
I am a bit worried, sad or unhappy ❑

I am very worried, sad or unhappy ❑

Please complete this on behalf of your child, but with your child's help where possible



The best health I can imagine



The worst health I can imagine

We would like to know how good or bad your childs health is TODAY

- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
- 0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your child's health is TODAY.

Section A is complete.
Please start day 1 of the diary (section B) tonight and then each evening. Thank you.

SECTION B - Daily Symptom Diary. Fill this out with your child helping wherever possible

Please start this diary today – the day you and your child have seen your GP or nurse (this is day 1). We will contact you on about day 3 to see if you have any questions. **This page is a <u>SAMPLE page to give you an idea of how to fill in the diary</u>**

For each day, you give every symptom a score from 0 to 6 **until you score 0 for all symptoms, or** until it is day 28.

SCORE	Severity of symptom
0	Normal/not affected
1	Very little problem
2	Slight problem
3	Moderately bad
4	Bad
5	Very bad
6	As bad as it could be

EXAMPLE: For a cough that is 'as bad as it' could be for the first 2 days then gradually starts to improve but is still present on day 7, and phlegm which is 'very bad' on day 1 but improves quickly and is completely gone by day 5, and no other symptoms.

Symptoms	***Day 1***	***Day 2***	***Day 3***	***Day 4***	***Day 5***	***Day 6***	***Day 7***
Cough	*6*	*6*	*5*	*4*	*4*	*4*	*3*
Phlegm	*5*	*3*	*3*	*1*	*0*	*0*	*0*
Shortness of breath	*0*	*0*	*0*	*0*	*0*	*0*	*0*
Wheeze	*0*	*0*	*0*	*0*	*0*	*0*	*0*
Blocked/runny nose	*0*	*0*	*0*	*0*	*0*	*0*	*0*
Chest pain	*0*	*0*	*0*	*0*	*0*	*0*	*0*
Fever (high temperature)	*0*	*0*	*0*	*0*	*0*	*0*	*0*
Muscle aching	*0*	*0*	*0*	*0*	*0*	*0*	*0*
Headache	*0*	*0*	*0*	*0*	*0*	*0*	*0*
Disturbed sleep	*0*	*0*	*0*	*0*	*0*	*0*	*0*
Feeling generally unwell	*0*	*0*	*0*	*0*	*0*	*0*	*0*
Interference with normal activities/ work	*0*	*0*	*0*	*0*	*0*	*0*	*0*
Taken your study medication?	*Yes/no*	*Yes/no*	*Yes/no*	*Yes/no*	*Yes/no*	*Yes/no*	*Yes/no*
If yes please confirm how many doses you have taken (1, 2 or 3)	*2*	*3*	*3*	*2*			

Daily Symptom Diary - Please complete every day starting from (DAY & DATE)

For each day, please give every symptom a score from 0 to 6 **until you score 0 for all symptoms, or** until it is day 28. If you do score 0 for all symptoms please then complete the questions for the end of week 1 (starting on page 11) and then the Final questionnaire page 28.

SCORE	Severity of symptom
0	Normal/not affected
1	Very little problem
2	Slight problem
3	Moderately bad
4	Bad
5	Very bad
6	As bad as it could be

Symptoms	Day 1*	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7**
Cough							
Phlegm							
Shortness of breath							
Wheeze							
Blocked/runny nose							
Chest pain							
Fever (high temperature)							
Muscle aching							
Headache							
Disturbed sleep							
Feeling generally unwell							
Interference with normal activities/ work							
Interference with social activities							
Taken your study medication?	Yes/no	Yes/no	Yes/no	Yes/no	Yes/no	Yes/no	Yes/no

If yes please confirm how many doses you have taken (1, 2 or 3)							

* Please note, day 1 is the day that you saw your GP or nurse, not the first day of this illness.

**** ATTENTION**: Please complete the additional questions on the next two pages on day 7.

When you have got to day 7 please answer the end of week questions in the two pages starting on page 11.

Quality of life
Please complete on day 7

Please fill in this page in behalf of your child but with your child's help where possible

Describing your child's health TODAY

Under each heading, please tick the ONE box that best describes your child's health TODAY.

Mobility *(walking about)*

I have no problems walking about ❑

I have some problems walking about ❑

I have a lot of problems walking about ❑

Looking after myself

I have no problems washing or dressing myself ❑

I have some problems washing or dressing myself ❑

I have a lot of problems washing or dressing myself ❑

Doing usual activities *(for example, going to school, hobbies, sports, playing, doing things with family or friends)*

I have no problems doing my usual activities ❑

I have some problems doing my usual activities ❑

I have a lot of problems doing my usual activities ❑

Having pain or discomfort

I have no pain or discomfort ❑

I have some pain or discomfort ❑

I have a lot of pain or discomfort ❑

Feeling worried, sad or unhappy

I am not worried, sad or unhappy ❑

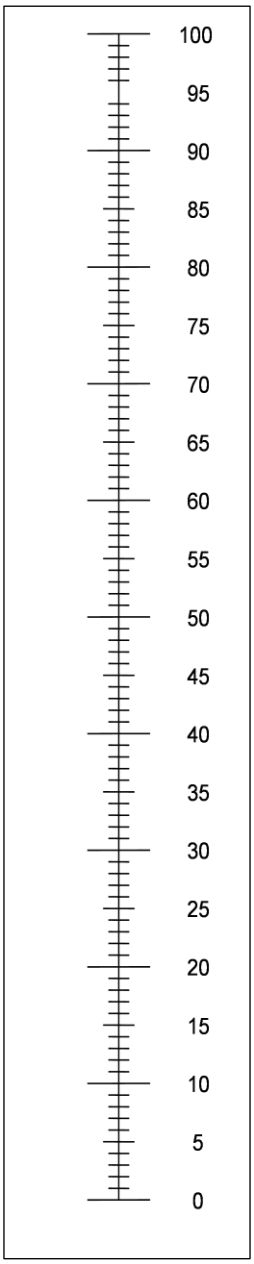
I am a bit worried, sad or unhappy ❑

I am very worried, sad or unhappy ❑

Please complete on day 7

Please complete this on behalf of your child but with your child's help where possible

The best health I can imagine



The worst health I can imagine

We would like to know how good or bad your childs health is TODAY

- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
- 0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your child's health is TODAY.

Week 1 Questionnaire – please complete on day 7 (Day and date)

1. In the last week, has your child been unable to attend nursery/daycare/childminder as a result of his/her cough/chest infection?
   No ☐ Yes ☐ If yes, number of days missed ☐

2. In the last week have you been unable to attend work or college because of your child's illness?
   No ☐ Yes ☐ If yes, number of days ___or hours ___missed?

3. In the last week have you had to arrange/pay for additional care because of your child's illness?
   No ☐ Yes ☐ If yes, number of days ___or hours ___

4. Has your child had diarrhoea in the last week?
   No ☐ Yes ☐

5. Has your child had any nausea/sickness in the last week?
   No ☐ Yes ☐

6. Has your child had a skin rash in the last week?
   No ☐ Yes ☐

   If yes, please specify _____

7. Has your child taken medicine, *other than the study medication*, for his/her cough / chest infection during the last week? (including increased dosage of their inhalation medication)
   No ☐ Yes ☐

If Yes, please give the details and tick each study day they took each medicine in the table on the next page:

Medication	Please tick	Number of doses per day	Tick if prescribed	Day						
				1	2	3	4	5	6	7
Paracetamol										
Ibuprofen										
Other pain medication										
Antibiotic										
Inhaled medication										
Cough medicine										
Lozenges / Mouth washes / gargles										
Nose spray										
Ear drops										
Herbal/ Complementary medicines										
Vitamins										

The questions for week 1 are now complete. Please continue completing the daily diary tomorrow.

Daily Symptoms Diary continued - DAY 8 to DAY 14

For each day, please give every symptom a score from 0 to 6 **until you score 0 for all symptoms, or** until it is day 28. If you score 0 for all symptoms please complete the questions for end of Week 2 questions on pages 15 to 18 and then the Final questionnaire page 28.

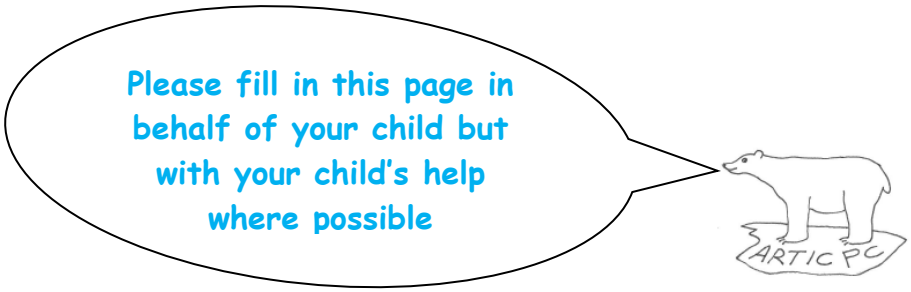
SCORE	Severity of symptom
0	Normal/not affected
1	Very little problem
2	Slight problem
3	Moderately bad
4	Bad
5	Very bad
6	As bad as it could be

Symptoms	Day 8*	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14**
Cough							
Phlegm							
Shortness of breath							
Wheeze							
Blocked/runny nose							
Chest pain							
Fever (high temperature)							
Muscle aching							
Headache							
Disturbed sleep							
Feeling generally unwell							
Interference with normal activities/ work							
Interference with social activities							

* Please note, day 8 is one week after your child saw your GP or nurse.

**** ATTENTION**: Please complete the questions for the end of week 2 in the next 4 pages

Please complete on day 14



Describing your child's health TODAY

Under each heading, please tick the ONE box that best describes your health TODAY.

Mobility *(walking about)*

I have no problems walking about ❑

I have some problems walking about ❑

I have a lot of problems walking about ❑

Looking after myself

I have no problems washing or dressing myself ❑

I have some problems washing or dressing myself ❑

I have a lot of problems washing or dressing myself ❑

Doing usual activities *(for example, going to school, hobbies, sports, playing, doing things with family or friends)*

I have no problems doing my usual activities ❑

I have some problems doing my usual activities ❑

I have a lot of problems doing my usual activities ❑

Having pain or discomfort

I have no pain or discomfort ❑

I have some pain or discomfort ❑

I have a lot of pain or discomfort ❑

Feeling worried, sad or unhappy

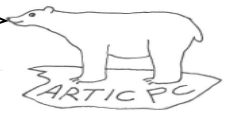
I am not worried, sad or unhappy ❑

I am a bit worried, sad or unhappy ❑

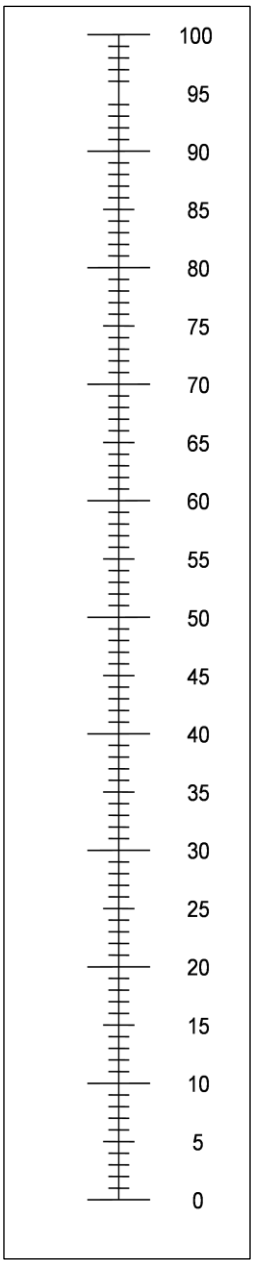
I am very worried, sad or unhappy ❑

Please complete on day 14

Please complete this on behalf of your child but with your child's help where possible



The best health I can imagine



The worst health I can imagine

We would like to know how good or bad your childs health is TODAY

- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
- 0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your child's health is TODAY.

Week 2 Questionnaire - Please complete on day 14 (Day & Date)

1. In the last week, has your child been unable to attend nursery/daycare/childminder as a result of his/her cough/chest infection?
   No ☐ Yes ☐ If yes, number of days missed ☐

2. In the last week have you been unable to attend work or college because of your child's illness?
   No ☐ Yes ☐ If yes, number of days ___or hours ___missed?

3. In the last week have you had to arrange/pay for additional care because of your child's illness?
   No ☐ Yes ☐ If yes, number of days ___or hours ___

4. Has your child had diarrhoea in the last week?
   No: ☐ Yes: ☐

5. Has your child had any nausea/sickness in the last week?
   No: ☐ Yes: ☐

6. Has your child had a skin rash in the last week?
   No: ☐ Yes: ☐
   If yes, please specify _____

7. Has your child taken medicine, *other than the study medication*, for his/her cough / chest infection during the last week? (including increased dosage of their inhalation medication) No: ☐ Yes: ☐
   If Yes, please give the details and tick each study day they took each medicine in the table on the next page:

Medication	Please tick	Number of doses per day	Tick if prescribed	Day						
				1	2	3	4	5	6	7
Paracetamol										
Ibuprofen										
Other pain medication										
Antibiotic										
Inhaled medication										
Cough medicine										
Lozenges / Mouth washes / gargles										
Nose spray										
Ear drops										
Herbal/ Complementary medicines										
Vitamins										

The questions for week 2 are now complete. Please continue completing the daily diary tomorrow.

Daily Symptoms Diary continued - DAY 15 to DAY 21

For each day, please give every symptom a score from 0 to 6 **until you score 0 for all symptoms, or** until it is day 28. If you score 0 for all symptoms please then complete the questions for the end of week 3 on this and the next 4 pages and then the Final questionnaire page 28.

SCORE	Severity of symptom
0	Normal/not affected
1	Very little problem
2	Slight problem
3	Moderately bad
4	Bad
5	Very bad
6	As bad as it could be

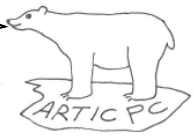
Symptoms	Day 15*	Day 16	Day 17	Day 18	Day 19	Day 20	Day 21**
Cough							
Phlegm							
Shortness of breath							
Wheeze							
Blocked/runny nose							
Chest pain							
Fever (high temperature)							
Muscle aching							
Headache							
Disturbed sleep							
Feeling generally unwell							
Interference with normal activities/ work							
Interference with social activities							

* Please note, day 15 is two weeks after your child saw your GP or nurse.

**** ATTENTION:** Please complete the week 3 questionnaire on the next 4 pages.

Please complete on day 21

Please fill in this page in behalf of your child but with your child's help where possible



Describing your child's health TODAY

Under each heading, please tick the ONE box that best describes your health TODAY.

Mobility *(walking about)*

I have no problems walking about ❑

I have some problems walking about ❑

I have a lot of problems walking about ❑

Looking after myself

I have no problems washing or dressing myself ❑

I have some problems washing or dressing myself ❑

I have a lot of problems washing or dressing myself ❑

Doing usual activities *(for example, going to school, hobbies, sports, playing, doing things with family or friends)*

I have no problems doing my usual activities ❑

I have some problems doing my usual activities ❑

I have a lot of problems doing my usual activities ❑

Having pain or discomfort

I have no pain or discomfort ❑

I have some pain or discomfort ❑

I have a lot of pain or discomfort ❑

Feeling worried, sad or unhappy

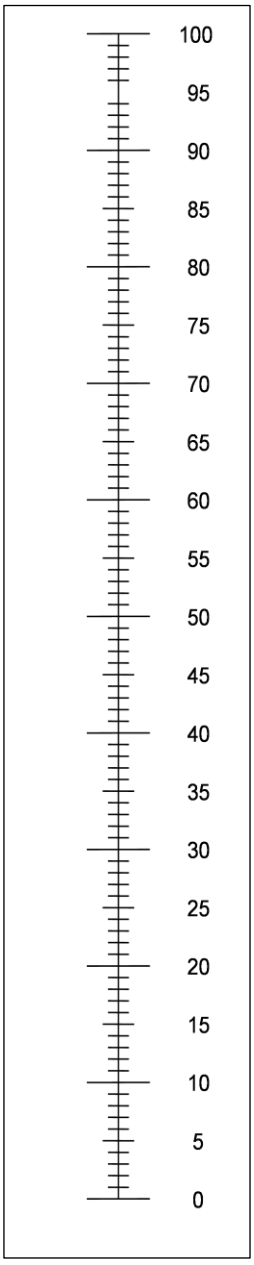
I am not worried, sad or unhappy ❑

I am a bit worried, sad or unhappy ❑

I am very worried, sad or unhappy ❑

Please complete this on behalf of your child but with your child's help where possible

The best health I can imagine



The worst health I can imagine

We would like to know how good or bad your childs health is TODAY

- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
- 0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your child's health is TODAY.

Week 3 Questionnaire - Please complete on day 21 (Day & Date)

1. In the last week, has your child been unable to attend nursery/daycare/childminder as a result of his/her cough/chest infection?

   No ☐ Yes ☐ If yes, number of days missed ☐

2. In the last week have you been unable to attend work or college because of your child's illness?

   No ☐ Yes ☐ If yes, number of days ___or hours ___missed?

3. In the last week have you had to arrange/pay for additional care because of your child's illness?

   No ☐ Yes ☐ If yes, number of days ___or hours ___

4. Has your child taken medicine, *other than the study medication*, for his/her cough / chest infection during the last week? (including increased dosage of their inhalation medication)

   No ☐ Yes ☐

If Yes, please give the details and tick each study day they took each medicine in the table on the next page:

Medication	Please tick	Number of doses per day	Tick if prescribed	Day						
				1	2	3	4	5	6	7
Paracetamol										
Ibuprofen										
Other pain medication										
Antibiotic										
Inhaled medication										
Cough medicine										
Lozenges / Mouth washes / gargles										
Nose spray										
Ear drops										
Herbal/ Complementary medicines										
Vitamins										

The questions for week 3 are now complete. Please continue completing the daily diary tomorrow.

Daily Diary Symptom continued - DAY 22 to DAY 28

For each day, please give every symptom a score from 0 to 6 **until you score 0 for all symptoms, or** until it is day 28. Please complete this table, the weekly questions pages 25-27 and then the Final questionnaire page 28.

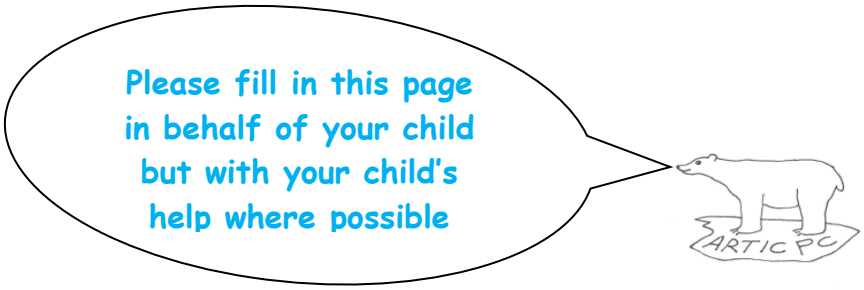
SCORE	Severity of symptom
0	Normal/not affected
1	Very little problem
2	Slight problem
3	Moderately bad
4	Bad
5	Very bad
6	As bad as it could be

Symptoms	Day 22*	Day 23	Day 24	Day 25	Day 26	Day 27	Day 28**
Cough							
Phlegm							
Shortness of breath							
Wheeze							
Blocked/runny nose							
Chest pain							
Fever (high temperature)							
Muscle aching							
Headache							
Disturbed sleep							
Feeling generally unwell							
Interference with normal activities/ work							
Interference with social activities							

* Please note, day 22 is three weeks after you saw your GP or nurse.

**** ATTENTION**: Please complete the week 4 questions on the next 3 pages and then the final questionnaire (page 28)

Please complete on day 28



Describing your child's health TODAY

Under each heading, please tick the ONE box that best describes your health TODAY.

Mobility *(walking about)*

I have no problems walking about ❑

I have some problems walking about ❑

I have a lot of problems walking about ❑

Looking after myself

I have no problems washing or dressing myself ❑

I have some problems washing or dressing myself ❑

I have a lot of problems washing or dressing myself ❑

Doing usual activities *(for example, going to school, hobbies, sports, playing, doing things with family or friends)*

I have no problems doing my usual activities ❑

I have some problems doing my usual activities ❑

I have a lot of problems doing my usual activities ❑

Having pain or discomfort

I have no pain or discomfort ❑

I have some pain or discomfort ❑

I have a lot of pain or discomfort ❑

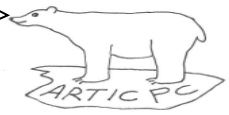
Feeling worried, sad or unhappy

I am not worried, sad or unhappy ❑

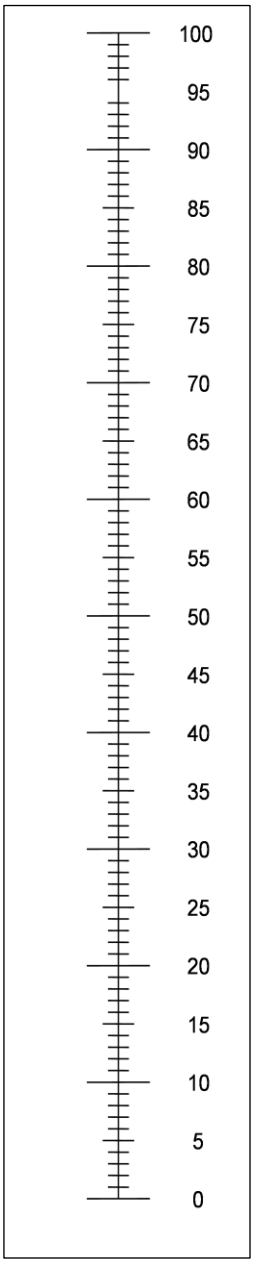
I am a bit worried, sad or unhappy ❑

I am very worried, sad or unhappy ❑

Please complete this on behalf of your child, but with your child's help where possible



The best health I can imagine



The worst health I can imagine

We would like to know how good or bad your childs health is TODAY

- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
- 0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your child's health is TODAY.

Week 4 – Please <u>complete on day 28</u> (Day & Date)

1. In the last week, has your child been unable to attend nursery/daycare/childminder as a result of his/her cough/chest infection?
   No ☐ Yes ☐ If yes, number of days missed ☐

2. In the last week have you been unable to attend work or college because of your child's illness?
   No ☐ Yes ☐ If yes, number of days ___or hours ___missed?

3. In the last week have you had to arrange/pay for additional care because of your child's illness?
   No ☐ Yes ☐ If yes, number of days ___or hours ___

4. Has your child taken medicine, *other than the study medication*, for his/her cough / chest infection during the last week? (including increased dosage of their inhalation medication)

   No ☐ Yes ☐

If Yes, please give the details and tick each study day they took each medicine in the table below:

Medication	Please tick	Number of doses per day	Tick if prescribed	Day 1	2	3	4	5	6	7
Paracetamol										
Ibuprofen										
Other pain medication										
Antibiotic										

Inhaled medication										
Cough medicine										
Lozenges / Mouth washes / gargles										
Nose spray										
Ear drops										
Herbal/ Complementary medicines										
Vitamins										

SECTION C: Final Questionnaire

Please complete on Day 28.

Please answer these questions once '0' has been scored for all daily symptoms, or it is day 28.

1. Overall, on what day did you feel your child recovered (the day your child started the diary was day 1, please state the number of the day that you think your child recovered. If they are not yet recovered, please answer not applicable N/A).

   Day number ☐

2. Since the visit to your GP/nurse on day 1, has your child been admitted to hospital for this illness?

   No ☐ Yes ☐

   If yes, please fill in the form below:

Number of admissions	Ward of admission	Data of admission (DD,MM,YY)	Nights of intensive care used	Date of discharge (DD, MM, YY)
1				
2				
3				

3. Since the visit to your GP/nurse on day 1, has your child revisited the GP about this illness?

   No ☐ Yes ☐

   If yes, please fill in the form below:

	Date of the visits	Place of visits (GP, telephone or home)	Who they see (GP, Nurse or both)	Reason for visit
1				
2				
3				

4. Since the visit to your GP/nurse on day 1, has your child visited any of the following about this illness?

	Reason for visit	Date of the visit	Who they saw	Times of visits
A and E attendance				
Walk in clinic				
Out of hour clinic				
Hospital admission				
NHS Direct				
Pharmacist				
Other please specify				

5. If you were taking the study medication please tick which medication you think your child received?

   Antibiotic (Amoxicillin) ☐ or Placebo/dummy medicine ☐

   Please give your reasons for your answer?

   _____

   _____

Thank you for completing the questionnaire!

Please return the questionnaire diary and any unused medication to the nurse when you return for your child's check up visit at 28 days.

Please use the box below to add any other comments you may have about this research

Thank you very much for completing the symptom diary and questions.
If you have any problems or queries, please contact [name NNF]