Follow-up

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PediCAP is part of the EDCTP2 programme supported by the European Union under Grant Agreement RIA2017MC - 2023.

Summary

- Overview of follow-up visits
- In-hospital visits
- Post-discharge visits

Follow-up visits

- Patients should be followed up as per the Individual Patient Visit Schedule generated by the database at randomisation.
- The following visits should be conducted:
  - In hospital: daily face-to-face assessments until discharge
  - Day of discharge: face-to-face assessment
  - Week 1, 2 and 3: telephone call assessment (or face-to-face if usual practice or still in hospital)
  - Week 4: face-to-face assessment
  - Acute events: face-to-face assessment if child attends site due to an event.

Trial Assessment Schedule

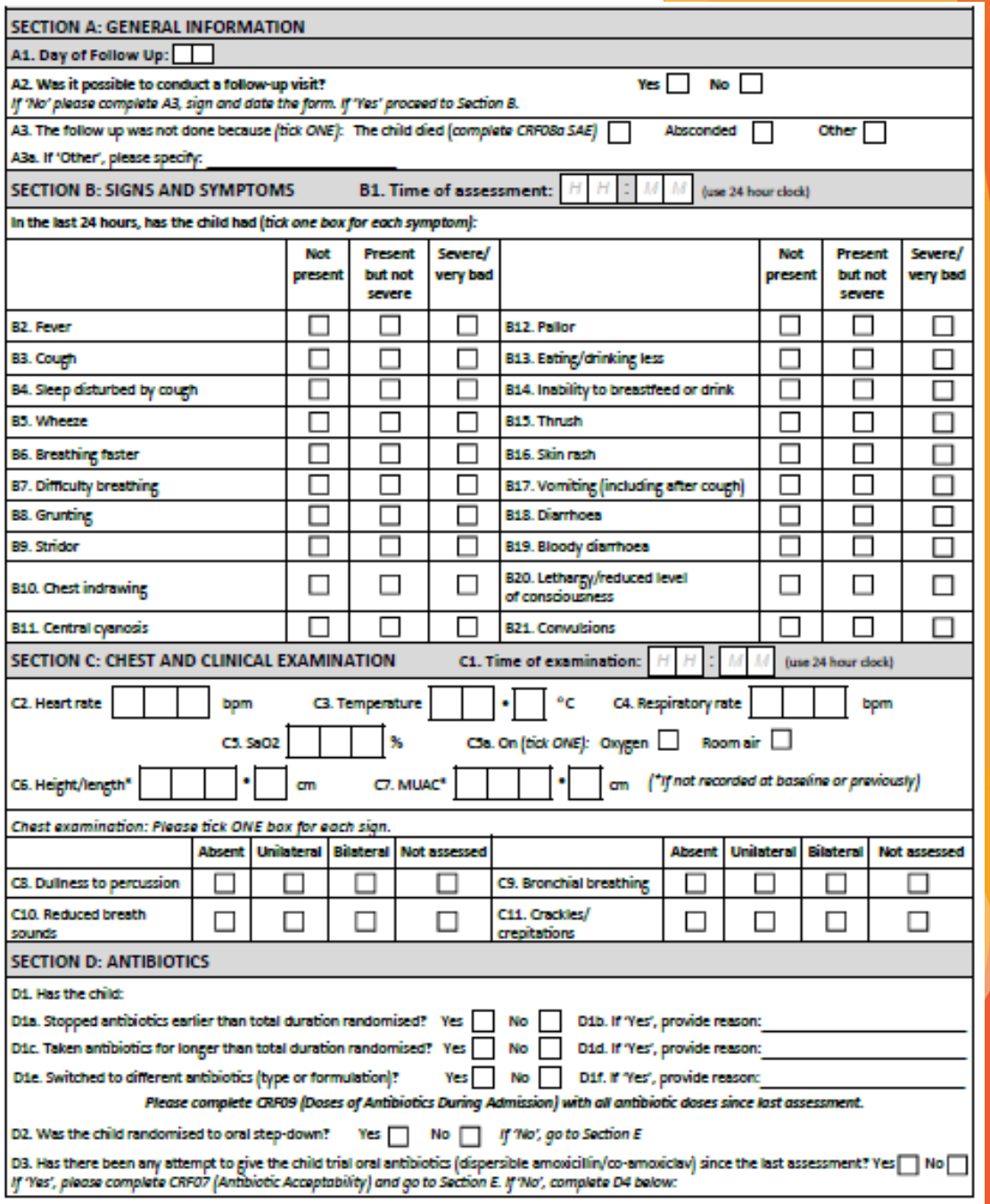
ASSESSMENTS (PediCAP-A and PediCAP-B) Face-to-face (f2f) ■ Face-to-face (f2f) or telephone □	DAYS IN TRIAL (d)									
	Screening d-1 to d1	Randomisation d1	Daily until discharge	Oral step-down	At discharge	Week 1 d8-10	Week 2 d15-17	Week 3 d22-24	Week 4 d27-34	Any acute event
Trial participation										
Parent/Carer information sheet	X	X								
Informed consent	X	X								
Drug supply dispensing				X†						
Adherence and tolerability[a]					X	X				
Clinical assessment										
Baseline data collection[b]		X								
Weight		X		X					X	
Vital signs[c]		X	X		X					X[d]
Symptoms and clinical signs[e]		X	X		X	X	X	X	X	X[d]
Concomitant care/healthcare utilisation[f]			X		X	X	X	X	X	X[d]
Laboratory assessment										
Point of care C-Reactive Protein[g]	X									
Haematology[h]		(X)	(X)			(X)	(X)	(X)	(X)	(X)
Biochemistry[i]		(X)	(X)			(X)	(X)	(X)	(X)	(X)
Microbiological investigations[j]		(X)	(X)			(X)	(X)	(X)	(X)	(X)
Radiological assessment										
Chest X-ray[k]		(X)	(X)							(X)
PK substudy: additional tests										
Pharmacokinetics samples[l] (total 10ml)				X						
Microbiology substudy: additional tests										
Peri-rectal swab[m]		X			X				X	
Nasopharyngeal swab[n]		X			[X][n]				[X][n]	

In-hospital visits

- A patient should have a face-to-face study follow-up visit every day that they are in hospital.
- The following assessments should be carried out at the daily follow-up in hospital visits:
  - Assessment of **symptoms** and **clinical signs** (such as fever, cough, shortness of breath)
  - **Chest** and **clinical examination** (including vital signs and temperature)
  - **Antibiotics** assessment
  - **Serious** or **non-serious adverse events**
  - **Notable events** (overdose, abuse or misuse of IMP)
  - Changes to **concomitant medication**
  - Routine haematology, biochemistry, microbiology, respiratory tests or x-rays are not required for research purposes but should be reported if completed.

CRF05 – Follow up-In Hospital

- In hospital visits should be recorded on CRF05 – Follow up-In Hospital.



SECTION A: GENERAL INFORMATION

A1. Day of Follow Up: ☐☐

A2. Was it possible to conduct a follow-up visit? Yes ☐ No ☐
If 'No' please complete A3, sign and date the form. If 'Yes' proceed to Section B.

A3. The follow up was not done because (*tick ONE*): The child died (*complete CRF08a SAE*) ☐ Absconded ☐ Other ☐

A3a. If 'Other', please specify: _____

SECTION B: SIGNS AND SYMPTOMS B1. Time of assessment: H H : M M (use 24 hour clock)

In the last 24 hours, has the child had (*tick one box for each symptom*):

	Not present	Present but not severe	Severe/ very bad		Not present	Present but not severe	Severe/ very bad
B2. Fever	☐	☐	☐	B12. Pallor	☐	☐	☐
B3. Cough	☐	☐	☐	B13. Eating/drinking less	☐	☐	☐
B4. Sleep disturbed by cough	☐	☐	☐	B14. Inability to breastfeed or drink	☐	☐	☐
B5. Wheeze	☐	☐	☐	B15. Thrush	☐	☐	☐
B6. Breathing faster	☐	☐	☐	B16. Skin rash	☐	☐	☐
B7. Difficulty breathing	☐	☐	☐	B17. Vomiting (including after cough)	☐	☐	☐
B8. Grunting	☐	☐	☐	B18. Diarrhoea	☐	☐	☐
B9. Stridor	☐	☐	☐	B19. Bloody diarrhoea	☐	☐	☐
B10. Chest indrawing	☐	☐	☐	B20. Lethargy/reduced level of consciousness	☐	☐	☐
B11. Central cyanosis	☐	☐	☐	B21. Convulsions	☐	☐	☐

SECTION C: CHEST AND CLINICAL EXAMINATION C1. Time of examination: H H : M M (use 24 hour clock)

C2. Heart rate ☐☐☐ bpm C3. Temperature ☐☐ • ☐ °C C4. Respiratory rate ☐☐☐ bpm

C5. SaO2 ☐☐☐ % C5a. On (*tick ONE*): Oxygen ☐ Room air ☐

C6. Height/length* ☐☐☐ • ☐ cm C7. MUAC* ☐☐☐ • ☐ cm (*If not recorded at baseline or previously)

Chest examination: Please tick ONE box for each sign.

	Absent	Unilateral	Bilateral	Not assessed		Absent	Unilateral	Bilateral	Not assessed
C8. Dullness to percussion	☐	☐	☐	☐	C9. Bronchial breathing	☐	☐	☐	☐
C10. Reduced breath sounds	☐	☐	☐	☐	C11. Crackles/ crepitations	☐	☐	☐	☐

SECTION D: ANTIBIOTICS

D1. Has the child:

D1a. Stopped antibiotics earlier than total duration randomised? Yes ☐ No ☐ D1b. If 'Yes', provide reason: _____

D1c. Taken antibiotics for longer than total duration randomised? Yes ☐ No ☐ D1d. If 'Yes', provide reason: _____

D1e. Switched to different antibiotics (type or formulation)? Yes ☐ No ☐ D1f. If 'Yes', provide reason: _____

Please complete CRF09 (Doses of Antibiotics During Admission) with all antibiotic doses since last assessment.

D2. Was the child randomised to oral step-down? Yes ☐ No ☐ *If 'No', go to Section E*

D3. Has there been any attempt to give the child trial oral antibiotics (dispersible amoxicillin/co-amoxiclav) since the last assessment? Yes ☐ No ☐
If 'Yes', please complete CRF07 (Antibiotic Acceptability) and go to Section E. If 'No', complete D4 below:

Post-discharge visits

- A patient should have a post discharge visit at week 1, week 2, week 3 and week 4.
- They will only move on to the post-discharge schedule after discharge.
- Whilst a patient is still in hospital, they will continue to be followed up with a daily face-to-face in-hospital follow up visit.

Post discharge visits - telephone

- The following assessments should be completed at follow-up post-discharge visits conducted over the telephone:
  - Standardised **symptom checklist** including review of cough, presence of rapid breathing, fever, general state and common known side effects of amoxicillin or co-amoxiclav).
  - Explicitly prompt for the following **clinical adverse events** since last protocol contact: rashes, diarrhoea, vomiting, gastrointestinal events, and thrush/candida.
  - **Antibiotics** assessment (including new prescriptions, tolerability and adherence) – completion of CRF07 – Antibiotics Acceptability at week 1 and week 2 if had not finished oral treatment at the previous visit.
  - **Concomitant care/healthcare utilisation** (including traditional healers).
  - **Serious, notable or non-serious adverse events.**
  - Changes to **concomitant medication.**

Post-discharge visits – face-to-face

- The following assessments should be carried out at face-to-face follow-up post-discharge visits:
  - Assessment of **symptoms** and **clinical signs** (such as fever, cough, shortness of breath).
  - **Chest** and **clinical examination** (including vital signs and temperature).
  - **Antibiotics** assessment (including new prescriptions, tolerability and adherence) - completion of CRF07 – Antibiotics Acceptability at week 1 and week 2 if had not finished oral treatment at the previous visit.
  - **Concomitant care/healthcare utilisation** (including traditional healers).
  - **Serious, notable or non-serious adverse events**.
  - Changes to **concomitant medication**.
  - Routine haematology, biochemistry, microbiology, respiratory tests or x-rays are not required for research purposes but should be reported if completed.

Week 3

- The parent/carer should be reminded of the importance of attending the week 4 visit in person (and to bring childs immunisation record at this visit if not already obtained).
- The date and time of the visit should be confirmed and may be re-arranged to ensure the visit is attended.
- They should also be reminded that the cost of transport will be reimbursed. The amount that this will be is listed in the Patient Information Sheet.

Week 4

- Additionally at week 4:
  - Weight
  - If the parent/carer did not bring the child's immunisation record at their original admission, they should be asked to bring it for copying.
  - The parent/carer should return any unused drug to the clinic.
  - Complete CRF16 – Cost to Families for Care and Treatment.

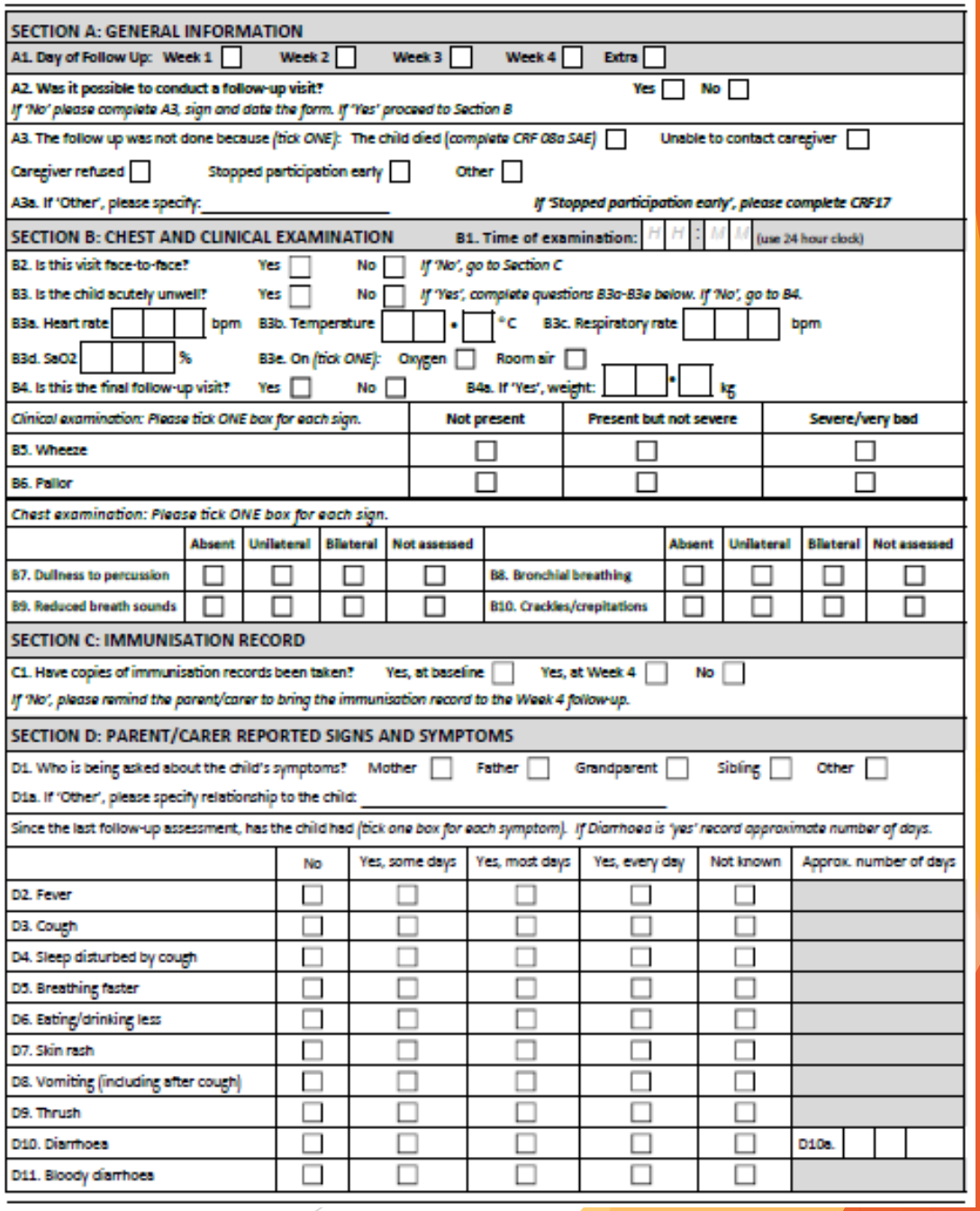
Target Dates

Visit Name	Visit Window	Type of Visit
Week 1	Day 8-10	Telephone
Week 2	Day 15-17	Telephone
Week 3	Day 22-24	Telephone
Week 4	Day 27-34	Face-to-face

- Target dates for these visits are determined by randomisation date and are not affected by subsequent events.
- This means that the week 1 visit will always occur 1 week after randomisation.
- Example:
  - A patient is still in hospital on the day of their scheduled week 1 visit. They should have the daily in-hospital visit rather than a week 1 visit.
  - The patient is discharged the next day. Their next visit will be their week 2 visit via telephone.

CRF06 – Follow up–Post Discharge

- Post discharge visits should be recorded on CRF06 – Follow up – Post Discharge



SECTION A: GENERAL INFORMATION

A1. Day of Follow Up: Week 1 ☐ Week 2 ☐ Week 3 ☐ Week 4 ☐ Extra ☐

A2. Was it possible to conduct a follow-up visit? Yes ☐ No ☐

If 'No' please complete A3, sign and date the form. If 'Yes' proceed to Section B

A3. The follow up was not done because (tick ONE): The child died (complete CRF 08a SAE) ☐ Unable to contact caregiver ☐

Caregiver refused ☐ Stopped participation early ☐ Other ☐

A3a. If 'Other', please specify: _____ *If 'Stopped participation early', please complete CRF17*

SECTION B: CHEST AND CLINICAL EXAMINATION B1. Time of examination: H H : M M (use 24 hour clock)

B2. Is this visit face-to-face? Yes ☐ No ☐ *If 'No', go to Section C*

B3. Is the child acutely unwell? Yes ☐ No ☐ *If 'Yes', complete questions B3a-B3e below. If 'No', go to B4.*

B3a. Heart rate ☐☐☐ bpm B3b. Temperature ☐☐.☐ °C B3c. Respiratory rate ☐☐☐ bpm

B3d. SaO2 ☐☐☐ % B3e. On (tick ONE): Oxygen ☐ Room air ☐

B4. Is this the final follow-up visit? Yes ☐ No ☐ B4a. If 'Yes', weight: ☐☐.☐ kg

Clinical examination: Please tick ONE box for each sign.	Not present	Present but not severe	Severe/very bad
B5. Wheeze	☐	☐	☐
B6. Pallor	☐	☐	☐

Chest examination: Please tick ONE box for each sign.

	Absent	Unilateral	Bilateral	Not assessed		Absent	Unilateral	Bilateral	Not assessed
B7. Dullness to percussion	☐	☐	☐	☐	B8. Bronchial breathing	☐	☐	☐	☐
B9. Reduced breath sounds	☐	☐	☐	☐	B10. Crackles/crepitations	☐	☐	☐	☐

SECTION C: IMMUNISATION RECORD

C1. Have copies of immunisation records been taken? Yes, at baseline ☐ Yes, at Week 4 ☐ No ☐

If 'No', please remind the parent/carer to bring the immunisation record to the Week 4 follow-up.

SECTION D: PARENT/CARER REPORTED SIGNS AND SYMPTOMS

D1. Who is being asked about the child's symptoms? Mother ☐ Father ☐ Grandparent ☐ Sibling ☐ Other ☐

D1a. If 'Other', please specify relationship to the child: _____

Since the last follow-up assessment, has the child had (tick one box for each symptom). *If Diarrhoea is 'yes' record approximate number of days.*

	No	Yes, some days	Yes, most days	Yes, every day	Not known	Approx. number of days
D2. Fever	☐	☐	☐	☐	☐	
D3. Cough	☐	☐	☐	☐	☐	
D4. Sleep disturbed by cough	☐	☐	☐	☐	☐	
D5. Breathing faster	☐	☐	☐	☐	☐	
D6. Eating/drinking less	☐	☐	☐	☐	☐	
D7. Skin rash	☐	☐	☐	☐	☐	
D8. Vomiting (including after cough)	☐	☐	☐	☐	☐	
D9. Thrush	☐	☐	☐	☐	☐	
D10. Diarrhoea	☐	☐	☐	☐	☐	D10a. ☐☐☐
D11. Bloody diarrhoea	☐	☐	☐	☐	☐	

What if the child is still in hospital on Day 28?

- If the child is in hospital on day 28 (either still admitted from randomisation, or re-admitted) the last follow-up visit will take place on this date.
- When the child is discharged at a later date, a CRF06-Follow up-post discharge should be submitted on the day of discharge.
- Only the discharge date is required to be completed on this extra form.
- This is so that the total duration of hospitalisation can still be collected