

## ECFSPR ENCOUNTER VARIABLES (vs 1.1)

Field Name	Chapter title	Sub chapter title	Coding
Name Clinic (for visit)	Date		
Date of Encounter	Date		Calendar to select date: dd/mm/yyyy
Doctor	Date		open field
Weight (kg)	Respir/Nutrit		Numeric value in kg, to 1 decimal place (with point, not comma) (-1) Unknown (-99) Missing
Height (cm)	Respir/Nutrit		Numeric value in cm, without decimals (-1) Unknown (-99) Missing
Age as decimal (computed)			automatic calculation
Age in months (computed)			automatic calculation
Weight z-score	Respir/Nutrit		automatic calculation
Weight age percentile	Respir/Nutrit		automatic calculation
Height z-score	Respir/Nutrit		automatic calculation
Height age percentile	Respir/Nutrit		automatic calculation
BMI	Respir/Nutrit		automatic calculation
BMI z-score	Respir/Nutrit		automatic calculation
BMI percentile	Respir/Nutrit		automatic calculation
FEV1 (litres)	Respir/Nutrit		record value in litres (two decimals, use '.' for decimals) of FEV1% predicted according to local reference values; (1) If unknown or not collected.
FVC (litres)	Respir/Nutrit		record value in litres (two decimals, use '.' for decimals) of the FVC according to local reference values; (-1) Unkown (-99) Missing
Date of FEV1 measurement	Respir/Nutrit		dd/mm/yyyy
FEF 25-75 (litres)	Respir/Nutrit		open field Value in L/sec (-1) Unkown (-99) Missing
FEV1% of predicted	Respir/Nutrit		automatic calculation
FVC% of predicted	Respir/Nutrit		automatic calculation
FEV1 / FVC	Respir/Nutrit		automatic calculation
FEF 25-75% of predicted	Respir/Nutrit		automatic calculation

<b>Result of LCI 2.5%</b>	Respir/Nutrit		Value recorded at time of visit (-1) Unknown (-99) Missing	
<b>Month of LCI 2.5% measurement</b>	Respir/Nutrit		mm	
<b>Day of LCI 2.5% measurement</b>	Respir/Nutrit		dd	
<b>Device used for LCI measurement</b>	Respir/Nutrit		(0) Not done (-1) Unknown (-99) Missing Yes: (1) Ecomedics Exhalyzer D N2-Washout (2) Ecomedics Exhalyzer SF6 (Tracergas 4 %) (3) Innovision Innocor (4) NDD Easyone Pro	
<b>Seen by Physiotherapist</b>	Respir/Nutrit		(0) No (-1) Unknown (-99) Missing (1) Yes	
<b>Seen by Dietician</b>	Respir/Nutrit		(0) No (-1) Unknown (-99) Missing (1) Yes	
<b>Seen by Psychotherapist</b>	Respir/Nutrit		(0) No (-1) Unknown (-99) Missing (1) Yes	
<b>Maintenance Antibiotic</b>	Therapy	Maintenance Antibiotic	(0) No (-1) Unknown (-99) Missing (1) Yes	
<b>Nebulised Tobramycin</b>	Therapy	Maintenance Antibiotic	(0) No (-1) Unknown (-99) Missing Yes: (1) Continuously (2) Alternating monthly	If YES: Start & Stop dates / Continuing / Dosage
<b>Nebulised Colomycin</b>	Therapy	Maintenance Antibiotic	(0) No (-1) Unknown (-99) Missing Yes: (1) Continuously (2) Alternating monthly	If YES: Start & Stop dates / Continuing / Dosage
<b>Nebulised Aztreonam</b>	Therapy	Maintenance Antibiotic	(0) No (-1) Unknown (-99) Missing Yes: (1) Continuously (2) Alternating monthly	If YES: Start & Stop dates / Continuing / Dosage
<b>Nebulised Levofloxacin</b>			(0) No (-1) Unknown (-99) Missing Yes: (1) Continuously (2) Alternating monthly	If YES: Start & Stop dates / Continuing / Dosage

<b>Tobramycin dry powder inhaler</b>	Therapy	Maintenance Antibiotic	(0) No (-1) Unknown (-99) Missing Yes: (1) Continuously (2) Alternating monthly	If YES: Start & Stop dates / Continuing / Dosage
<b>Colomycin dry powder inhaler</b>	Therapy	Maintenance Antibiotic	(0) No (-1) Unknown (-99) Missing Yes: (1) Continuously (2) Alternating monthly	If YES: Start & Stop dates / Continuing / Dosage
<b>Nebulised / dry powder antibiotics - Other</b>	Therapy	Maintenance Antibiotic	(0) No (-1) Unknown (-99) Missing Yes: (1) Continuously (2) Alternating monthly	If YES: Start & Stop dates / Continuing / Dosage
<b>Name of nebulised / dry powder antibiotics - Other</b>	Therapy	Maintenance Antibiotic	open field.	
<b>Azithromycin / Macrolide Maintenance Therapy</b>	Therapy	Maintenance Antibiotic	(0) No (-1) Unknown (-99) Missing Yes: (1) Azithromycine (2) Erythromycine (3) Clarithromycin]	If YES: Start & Stop dates / Continuing / Dosage
<b>Chronic oral antibiotics</b>	Therapy	Maintenance Antibiotic	(0) No (-1) Unknown (-99) Missing Yes: (1) Quinolone (Ciprofloxacin, Moxifloxacin, Levofloxacin, etc.) (2) Sulphonamide (trimethoprim/ sulfamethoxazole) (3) Cephalosporin (cephalexin, cefuroxime, cefaclor, etc.) (4) Penicillin (amoxicillin (including amoxicillin combination with clavulanic acid) (5) Flucloxacillin etc. (6) Tetracycline (doxycycline, minocycline etc) (7) Metronidazole (8) Clindamycin (9) Rifampicin (10) Sodium fusidate (11) Chloramphenicol (12) Other + open field	If YES: Start & Stop dates / Continuing / Dosage

<b>Chronic antifungal therapy</b>	Therapy	Maintenance Antibiotic	(0) No (-1) Unknown (-99) Missing Yes: (1) Itraconazole (2) Voriconazole (3) Posaconazole (4) Other + open field	If YES: Start & Stop dates / Continuing / Dosage
<b>Use of rhDNase</b>	Therapy	Respiratory	(0) No (-1) Unknown (-99) Missing (1) Yes	If YES: Start & Stop dates / Continuing / Dosage
<b>Hypertonic saline</b>	Therapy	Respiratory	(0) No (-1) Unknown (-99) Missing (1) 3% (2) 7%	If YES: Start & Stop dates / Continuing / Dosage
<b>Use of Mannitol</b>	Therapy	Respiratory	(0) No (-1) Unknown (-99) Missing (1) Yes	If YES: Start & Stop dates / Continuing / Dosage
<b>Inhaled short acting bronchodilators</b>	Therapy	Respiratory	(0) No (-1) Unknown (-99) Missing Yes: (1) Salbuterol (2) Terbutaline (3) Other	If YES: Start & Stop dates / Continuing / Dosage
<b>Inhaled long acting bronchodilators</b>	Therapy	Respiratory	(0) No (-1) Unknown (-99) Missing Yes: (1) Salbuterol (2) Other	If YES: Start & Stop dates / Continuing / Dosage
<b>Inhaled steroid alone</b>	Therapy	Respiratory	(0) No (-1) Unknown (-99) Missing Yes: (1) Fluticasone (2) Budesonide (3) Beclomethasone (4) Other	If YES: Start & Stop dates / Continuing / Dosage
<b>Inhaled steroid with LABA</b>	Therapy	Respiratory	(0) No (-1) Unknown (-99) Missing Yes: (1) Fluticasone - Salmeterol (2) Budesonide - Formoterol (3) Other	If YES: Start & Stop dates / Continuing / Dosage
<b>Inhaled LAMA</b>	Therapy	Respiratory	(0) No (-1) Unknown (-99) Missing Yes: (1) Tiotropium (2) Other	If YES: Start & Stop dates / Continuing / Dosage

<b>Inhaled nasal steroid</b>	Therapy	Respiratory	(0) No (-1) Unknown (-99) Missing (1) Yes	If YES: Start & Stop dates / Continuing / Dosage
<b>Oral steroid</b>	Therapy	Respiratory	(0) No (-1) Unknown (-99) Missing (1) Yes	If YES: Start & Stop dates / Continuing / Dosage
<b>High dose ibuprofen</b>	Therapy	Respiratory	(0) No (-1) Unknown (-99) Missing (1) Yes	If YES: Start & Stop dates / Continuing / Dosage
<b>Leukotrien receptor antagonist</b>	Therapy	Respiratory	(0) No (-1) Unknown (-99) Missing (1) Yes	If YES: Start & Stop dates / Continuing / Dosage
<b>Oxygen therapy</b>	Therapy	Respiratory	(0) No (-1) Unknown (-99) Missing Yes: (1) During exercise (2) At night time (3) Continuous (4) Other	If YES: Start & Stop dates / Continuing / Dosage
<b>Non-invasive positive pressure ventilation (NIPPV)</b>	Therapy	Respiratory	(0) No (-1) Unknown (-99) Missing Yes: (1) CPAP (contin. positive airway pressure) (2) BPAP (bi-level positive airway pressure)	If YES: Start & Stop dates / Continuing / Dosage
<b>Pancreatic enzyme replacement</b>	Therapy	Nutrition / GI	(0) No (-1) Unknown (-99) Missing (1) Yes	If YES: Start & Stop dates / Continuing / Dosage
<b>Ursodeoxycholic acid</b>	Therapy	Nutrition / GI	(0) No (-1) Unknown (-99) Missing (1) Yes	If YES: Start & Stop dates / Continuing / Dosage
<b>Proton pump inhibitors (PPI)</b>	Therapy	Nutrition / GI	(0) No (-1) Unknown (-99) Missing (1) Yes	If YES: Start & Stop dates / Continuing / Dosage
<b>H2 Blocker</b>	Therapy	Nutrition / GI	(0) No (-1) Unknown (-99) Missing (1) Yes	If YES: Start & Stop dates / Continuing / Dosage
<b>Appetite Stimulating Medication</b>	Therapy	Nutrition / GI	(0) No (-1) Unknown (-99) Missing (1) Yes	If YES: Start & Stop dates / Continuing / Dosage
<b>Enteral feeding</b>	Therapy	Nutrition / GI	(0) No (-1) Unknown (-99) Missing Yes: (1) PEG (2) NG	If YES: Start & Stop dates / Continuing / Dosage

<b>Vitamin A supplements</b>	Therapy	Nutrition / GI	(0) No (-1) Unknown (-99) Missing (1) Yes	If YES: Start & Stop dates / Continuing / Dosage
<b>Vitamin D supplements</b>	Therapy	Nutrition / GI	(0) No (-1) Unknown (-99) Missing (1) Yes	If YES: Start & Stop dates / Continuing / Dosage
<b>Vitamin E supplements</b>	Therapy	Nutrition / GI	(0) No (-1) Unknown (-99) Missing (1) Yes	If YES: Start & Stop dates / Continuing / Dosage
<b>Vitamin K supplements</b>	Therapy	Nutrition / GI	(0) No (-1) Unknown (-99) Missing (1) Yes	If YES: Start & Stop dates / Continuing / Dosage
<b>Hormonal contraception</b>	Therapy	Endocrine	(0) No (-1) Unknown (-99) Missing (1) Yes	
<b>Calcium supplementation</b>	Therapy	Endocrine	(0) No (-1) Unknown (-99) Missing (1) Yes	
<b>Antidepressants</b>	Therapy	Endocrine	(0) No (-1) Unknown (-99) Missing (1) Yes	If YES: Start & Stop dates / Continuing / Dosage
<b>Bisphosphonate</b>	Therapy	Endocrine	(0) No (-1) Unknown (-99) Missing (1) Yes	
<b>Insulin</b>	Therapy	Endocrine	(0) No (-1) Unknown (-99) Missing Yes: (1) Intermittant (2) Daily	If YES: Start & Stop dates / Continuing / Dosage
<b>Oral Hypoglycemic</b>	Therapy	Endocrine	(0) No (-1) Unknown (-99) Missing (1) Yes	If YES: Start & Stop dates / Continuing / Dosage
<b>CFTR modifier therapy</b>	Therapy	Other therapy	(0) No (-1) Unknown (-99) Missing Yes: (1) Ivacaftor (2) Orkambi (3) Symkevi (4) Other (specify) + text field	If YES: Start & Stop dates / Continuing / Dosage  If Yes: scrollbox
<b>Date of diagnosis of pulmonary exacerbation</b>	Exacerbation history		Date field DD/MM/YYYY (calendar)	
<b>Stop date of pulmonary exacerbation</b>	Exacerbation history		Date field DD/MM/YYYY (calendar)	
<b>Was patient treated with IV antibiotics for this Pulmonary Exacerbation?</b>	Exacerbation history		(0) No (-1) Unknown (-99) Missing (1) Yes	

<b>Was patient treated with Inhaled antibiotics for this Pulmonary Exacerbation?</b>	Exacerbation history		(0) No (-1) Unknown (-99) Missing (1) Yes	
<b>Was patient hospitalized for this Pulmonary Exacerbation?</b>	Exacerbation history		(0) No (-1) Unknown (-99) Missing (1) Yes	
<b>Oral antibiotic</b>	Exacerbation history		– Stop (selection of date) – Continuing – Antibiotic name (drop-down list) (1) Flucloxacillin (2) Other (please specify)] + open field (-1) Unknown (-99) Missing	Dropdownlist: Flucloxacillin Other (please specify)] + open field Unknown
<b>Inhaled antibiotic</b>	Exacerbation history		Start (selection of date) – Stop (selection of date) – Continuing – Antibiotic name (drop-down list) (1) Amikacin (2) Aztreonam (3) Colistin (4) Flucloxacillin (5) Tobramycin (6) Gentamicin (7) Vancomycin (8) Other (please specify)] + open field (-1) Unknown (-99) Missing	If YES drop-down list
<b>Intravenous</b>	Exacerbation history		Start (selection of date) – Stop (selection of date) – Continuing Drop-down list: (1) Amikacin (2) Aztreonam (3) Cefoxitin (4) Ceftazidime (5) Colistin (6) Flucloxacillin (7) Fosfamicin (8) Tobramycin (9) Gentamicin (10) Meropenem (11) Teicoplanin (12) Vancomycin (13) Cephadrine; (14) Other (please specify) + open field (-1) Unknown (-1) Unknown (-99) Missing	Drop-down list if YES

<b>Hospitalisation</b>	Exacerbation history		– Admission (date) – Discharge (date) – Continuing – Reason: (0) No (-1) Unknown (-99) Missing Yes: (1) CF Pulmonary exacerbation (2) Other - CF related (3) Other-non CF related (4) CF related-Hemoptysis (5) CF related-Distal Intestinal Obstruction (6) Elective Surgery (7) CF related-Pneumothorax (8) CF related-End Stage Lung Disease	
<b>Hospitalisation planned</b>	Exacerbation history		(0) No (-1) Unknown (-99) Missing (1) Yes	
<b>Hospitalisation admittance</b>	Exacerbation history		(0) No (-1) Unknown (-99) Missing Yes: (1) Clinic (2) Emergency Room	If YES, dropdown list: Clinic Emergency Room
<b>Hospitalisation in ICU</b>	Exacerbation history		(0) No (-1) Unknown (-99) Missing (1) Yes	Start & End date
<b>Sample type</b>	Microbiology		(0) No (-1) Unknown (-99) Missing Yes: (1) OP swab (2) Spontaneous sputum (3) Bronchoscopy (4) Induced sputum (5) Pharyngeal aspiration (6) Other	If YES Drop down list: OP swab Spontaneous sputum Bronchoscopy Induced sputum Pharyngeal aspiration Other
<b>Sample date</b>	Microbiology		Calendar to select date	
<b><i>Has the subject tested positive for any of the following:</i></b>				
<b>Mucoid Pseudomonas aeruginosa</b>	Microbiology		(0) No (-1) Unknown (-99) Missing (1) Yes (2) Pending results	
<b>Non-mucoid Pseudomonas aeruginosa</b>	Microbiology		(0) No (-1) Unknown (-99) Missing (1) Yes (2) Pending results	



<b>Staphylococcus aureus</b>	Microbiology		(0) No (-1) Unknown (-99) Missing (1) Yes (2) Pending results	
<b>MRSA</b>	Microbiology		(0) No (-1) Unknown (-99) Missing (1) Yes (2) Pending results	
<b>Burkholderia cepacia complex</b>	Microbiology		(0) No (-1) Unknown (-99) Missing (1) Yes (2) Pending results	
<b>Non-tuberculous mycobacteria</b>	Microbiology		(0) No (-1) Unknown (-99) Missing Yes: (1) MAC (2) Abscessus (3) Other	
<b>Was Non-tuberculous mycobacteria cultured?</b>			(0) No (-1) Unknown (-99) Missing (1) Yes	
<b>Stenotrophomonas maltophilia</b>	Microbiology		(0) No (-1) Unknown (-99) Missing (1) Yes (2) Pending results	
<b>Achromobacter species-xylooxidans</b>	Microbiology		(0) No (-1) Unknown (-99) Missing (1) Yes (2) Pending results	
<b>Haemophilus influenzae (any species)</b>	Microbiology		(0) No (-1) Unknown (-99) Missing (1) Yes (2) Pending results	
<b>Other bacteria or fungus</b>	Microbiology		(0) No (-1) Unknown (-99) Missing (1) Yes (please specify) + open field (2) Pending results	
<b>ABPA</b>	Complications of CF		(0) No (-1) Unknown (-99) Missing Yes: (1) ABPA (2) ABPA requiring treatment	– If yes: dropdownlist: ABPA; ABPA requiring treatment – Default: Unknown

<b>Asthma</b>	Complications of CF		(0) No (-1) Unknown (-99) Missing (1) Yes	
<b>DIOS</b>	Complications of CF		(0) No (-1) Unknown (-99) Missing Yes: (1) hospitalisation unknown (2) hospitalisation required (2) hospitalisation not required	
<b>Glucose tolerance test done</b>	Complications of CF		(0) No (-1) Unknown (-99) Missing (1) Normal 2) Impaired glucose tolerance (3) Diabetic (4) Fasting hyperglycaemia (5) Yes, Other	
<b>Pneumothorax requiring chest drain since last encounter</b>	Complications of CF		(0) No (-1) Unknown (-99) Missing (1) Yes	
<b>Liver GI disease</b>	Complications of CF		(0) No (-1) Unknown (1) Cirrhosis with portal hypertension 2) Cirrhosis without portal hypertension / hypersplenism (3) Cirrhosis portal hypertension unknown (4) Liver disease without cirrhosis (5) Variacel bleeding (-99) Missing	
<b>Hemoptysis more than 250ml since last encounter</b>	Complications of CF		(0) No (-1) Unknown (1) Yes (-99) Missing	
<b>Pancreatitis</b>	Complications of CF		(0) No (-1) Unknown (1) Yes (-99) Missing	
<b>Malignancy diagnosed since last encounter</b>	Complications of CF		(0) No (-1) Unknown (99) Missing (1) Colorectal cancer (2) Small bowel cancer (3) Lymphoid leukemia (4) Testicular cancer (5) Breast cancer (6) Cancer of the Thyroid (7) Type unknown (8) Other (+ free text field )	If YES drop-down list:

<b>Sinusitis</b>	Complications of CF		(0) No (-1) Unknown (-99) Missing (1) Yes	
<b>Osteoporosis</b>	Complications of CF		(0) No (-1) Unknown (-99) Missing (1) Yes	
<b>Osteopenia</b>	Complications of CF		(0) No (-1) Unknown (-99) Missing (1) Yes	
<b>Gastroesophageal reflux</b>	Complications of CF		(0) No (-1) Unknown (-99) Missing (1) Yes	
<b>Arthritis</b>	Complications of CF		(0) No (-1) Unknown (-99) Missing (1) Yes	
<b>Anxiety</b>	Complications of CF		(0) No (-1) Unknown (-99) Missing (1) Yes	
<b>Depression</b>	Complications of CF		(0) No (-1) Unknown (-99) Missing (1) Yes	
<b>Salt loss syndrome</b>	Complications of CF		(0) No (-1) Unknown (-99) Missing (1) Yes	

<b>Comorbidities</b>	Complications of CF		(0) No (-1) Unknown (-99) Missing Yes: (1) Cardiac Arrhythmias (2) Cardiovascular Disease (including Heart failure) (3) Cholesterolemia (4) Chronic Pain (5) Constipation (6) Eye Disease (7) Cataract (8) Gall stone (9) Hearing Los (10) Hypertension with cholesterolemia (11) Hypertension without cholesterolemia (12) Pulmonary Arteria (13) Hypertension (14) Infertility (15) Micro gall bladder (16) Nasal polyp (17) Rectal prolapse (18) Renal disease (19) Nephrolithiasis (20) Renal disease – Proteinuria (21) Renal disease – Proteinuria requiring dialysis (22) Renal disease – GFR <50% (23) Renal disease –	If YES drop-down list
<b>Date of lab sample:</b>	Liver Chemistries (LC)		dd/mm/YYYY	
<b>ALT - Result:</b>	Liver Chemistries (LC)			
<b>Unit:</b>	Liver Chemistries (LC)		U/L; µmol/L	
<b>AST – Result:</b>	Liver Chemistries (LC)			
<b>Unit:</b>	Liver Chemistries (LC)		U/L; µmol/L	
<b>GGT – Result:</b>	Liver Chemistries (LC)			
<b>Unit:</b>	Liver Chemistries (LC)		U/L; µmol/L	
<b>Alkaline Phosphatase – Result:</b>	Liver Chemistries (LC)			
<b>Unit:</b>	Liver Chemistries (LC)		U/L; µmol/L	
<b>BILIRUBIN – Result:</b>	Liver Chemistries (LC)			
<b>Unit:</b>	Liver Chemistries (LC)		U/L; µmol/L	
<b>Has the patient died since last encounter</b>	Vital status / Transplant	Vital Status	(-1) Unknown (0) He/she died (1) He/she is alive	
<b>Date of death</b>	Vital status / Transplant		Calendar to select date	

<b>Cause of death</b>	Vital status / Transplant		(1) Respiratory (2) Transplantation (3) Non-CF related (4) Liver GI (5) Trauma (6) Suicide (6) Non-CF related (7) Other (+ open text field) (-1) Unknown (-99) Missing (cause of death not collected)	
<b>Has the patient been assessed for, or had an active transplant since the last encounter</b>	Vital status / Transplant		(0) No (-1) Unknown (-99) Missing (1) Yes	
<b>Referred, awaiting assesment</b>	Vital status / Transplant	Lung / Liver / Kidney / Other	(0) No (-1) No known change (-99) Missing (1) Yes	
<b>Assessed, awaiting decision</b>	Vital status / Transplant	Lung / Liver / Kidney	(0) No (-1) No known change (-99) Missing (1) Yes	
<b>Decision made: unsuitable for listing</b>	Vital status / Transplant	Lung / Liver / Kidney	(0) No (-1) No known change (-99) Missing (1) Yes	
<b>Decision made: on active list</b>	Vital status / Transplant	Lung / Liver / Kidney	(0) No (-1) No known change (-99) Missing (1) Yes	
<b>Transplanted</b>	Vital status / Transplant	Lung / Liver / Kidney	(0) No (date of transplant + tickbox Re-transplant not visible) (-1) No known change (date of transplant + tickbox Re-transplant not visible) (1) Yes (date of transplant + tickbox Re-transplant will become visible)	
<b>Date of transplant</b>	Vital status / Transplant	Lung / Liver / Kidney	Calendar. Variable becomes visible when yes transplanted.	
<b>Re-transplant</b>	Vital status / Transplant	Lung / Liver / Kidney	Tick box	
<b>Transplant type</b>		Other transplant	Drop down list	
<b>Referred, awaiting assesment</b>	Vital status / Transplant	Other transplant	(0) No (-1) No known change (1) Yes	
<b>Assessed, awaiting decision</b>	Vital status / Transplant	Other transplant	(0) No (-1) No known change (1) Yes	
<b>Decision made: unsuitable for listing</b>	Vital status / Transplant	Other transplant	(0) No (-1) No known change (-99) Missing (1) Yes	

<b>Decision made: on active list</b>	Vital status / Transplant	Other transplant	(0) No (-1) No known change (-99) Missing (1) Yes	
<b>Transplanted</b>	Vital status / Transplant	Other transplant	(0) No (date of transplant + checkbox Re-transplant not visible) (-1) No known change (date of transplant + checkbox Re- transplant not visible) (1) Yes (date of transplant + checkbox Re-transplant will become visible)	
<b>Date of transplant</b>	Vital status / Transplant	Other transplant	Calendar	
<b>Re-transplant</b>	Vital status / Transplant	Other transplant	Field becomes visible when yes transplanted.	
<b>Did patient or caregiver reconsent/re-assent at any time?</b>	Re-consent / -Assent		(0) No (-1) No known change (-99) Missing (1) Yes	
<b>Date of written informed consent</b>	Re-consent / -Assent		dd/mm/yyyy	
<b>Informed CONSENT provided by:</b>	Re-consent / -Assent		(0) Patient (1) Caregiver	
<b>Did patient provide informed Assent?</b>	Re-consent / -Assent		(0) No (-1) No known change (-99) Missing (1) Yes	
<b>Date of informed Assent:</b>	Re-consent / -Assent		dd/mm/yyyy	Calendar
<b>Protocol version to which this consent/assent corresponds (please enter the version, e,g, 1.0, 2.0, etc.):</b>	Re-consent / -Assent		text field	