A National study of Nintedanib for Progressive Fibrosing Interstitial Lung Disease

1. AUDIT LOCATION

Name of Hospital…….

2. PATIENT DETAILS AND DEMOGRAPHICS

Local ID/MRN (e.g. RBH 001)……

Patient Initials……

Audit Number (to be assigned by RBH)……...

Age at initiation of nintedanib (years)					
Sex	M ☐	F ☐			
Ethnicity	White ☐	Black ☐	Asian ☐	Mixed ☐	Other ☐
Smoking	Current ☐	Ex ☐	Never ☐		
Height (m)					
BMI (kg/m2)					
Known to hospital or community palliative care services	Yes ☐		No ☐	Not Sure ☐	

3. DIAGNOSES

ILD diagnosis:

Chronic Hypersensitivity Pneumonitis	Yes ☐	No ☐			
Autoimmune ILD	Yes ☐	No ☐	If yes please specify		Tick
				Rheumatoid related ILD	☐
				Systemic sclerosis-associated ILD	☐
				Mixed connective tissue disease-associated ILD	☐
				Other autoimmune ILD	☐
Unclassifiable idiopathic interstitial pneumonia	Yes ☐	No ☐			
Idiopathic non-specific interstitial pneumonia	Yes ☐	No ☐			
Other	Yes ☐	No ☐	Please Specify		

Comorbidities

……
……
……
……
……
……
……

Medication

Medication (please include Nintedanib and dose)	Dose	Date commenced (Please only complete for immunosuppressive therapy; leave blank if unknown)

Immunomodulators (including steroids)

Was a new immunomodulator commenced after Nintedanib initiation?	Yes ☐		No ☐	Unknown ☐
	Drug(s)	Indication for starting		
Were any immunomodulators discontinued after Nintedanib initiation?	Yes ☐		No ☐	Unknown ☐
	Drug(s)	Indication for stopping		
Was the dose of immunomodulator changed after Nintedanib initiation?	Yes ☐		No ☐	Unknown ☐
	Drug(s)	Indication for change		

Severity of disease

MRC dyspnoea grade (1-5)				Not Known ☐
Home Oxygen	Yes ☐		No ☐	Not Known ☐
	Ambulatory ☐	LTOT ☐		
	Commenced prior to Nintedanib initiation ☐	Commenced after Nintedanib initiation ☐		
Was the patient ever	Yes ☐	Declined ☐	No ☐	Not Known ☐
		Under assessment ☐		

referred for transplant?		On active transplant waiting list ☐		

Family history

Does the patient have a familial history of ILD?	Yes ☐	No ☐	Unknown ☐	**IF YES** Specify type of ILD			
				First Degree Relatives		Second Degree Relatives	
				Yes ☐	No ☐	Yes ☐	No ☐

4. BASIS FOR ENTRY ONTO THE PROGRAMME – Please send anonymised Nintedanib initiation proforma

Date accepted onto the programme……

Date of initiation of Nintedanib……..

Indication for entry onto programme (select all that apply)	YES	NO	DETAILS
Progressive symptoms	☐	☐	
Progressive fibrosis on CT	☐	☐	
Progressive decline in lung function	☐	☐	
Increasing oxygen requirement	☐	☐	
Other (please specify)	☐	☐	

5. RADIOLOGY- Please attach anonymised reports of all previous CT scans

	Initial CT preceding nintedanib		CT at initiation of nintedanib (leave blank if no CT)		Follow up CT scan post nintedanib initiation (leave blank if no CT)	
Date of CT						
CT report						
Progression of fibrosis from previous CT?	YES ☐	NO ☐	YES ☐	NO ☐	YES ☐	NO ☐
Predominant radiological ILD pattern	Usual interstitial pneumonia (UIP)					☐
	Fibrotic non-specific interstitial pneumonia (NSIP)					☐
	Fibrotic hypersensitivity pneumonitis (HSP)					☐

	Fibrotic organising pneumonia (OP)	☐
	Fibrotic sarcoid	☐
	Other	☐ *(specify)*

6. LUNG FUNCTION – Please attach serial formal lung function reports including any tests performed prior to those entered in the table below

	24 months prior to Nintedanib initiation (+/- 6 months)	12 months prior to Nintedanib (+/- 6 months)	At initiation of Nintedanib (+/- 6 months)	12 months after initiation of Nintedanib (+/- 6 months)
Date of lung function				
Weight at time of test				
Height at time of test				
FEV_1 (L)				
FEV_1 (% predicted)				
FVC (L)				
FVC (% predicted)				
TLco				
TLco (% predicted)				
Kco				
Kco (% predicted)				

7. SYMPTOMATIC PROGRESSION

Please rate the patient's symptoms according to the following scale (leave blank if no data):

1: Rapid/severe deterioration

2: Mild/moderate deterioration

3: No change

4: Mild/moderate improvement

5: Significant improvement

	12 months preceding Nintedanib initiation	Since Nintedanib initiation
Dyspnoea	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Cough	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Exercise tolerance	☐ 1 ☐ 2 ☐ 3	☐ 1 ☐ 2 ☐ 3

	☐ 4 ☐ 5	☐ 4 ☐ 5
Other symptom related to ILD (specify)	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

Did the patient have a health-related quality of life score (e.g. K-BILD, EQ 5D)?

YES ☐ NO ☐

Name of score			
	12 months prior to Nintedanib (+/- 6 months)	At initiation of Nintedanib (+/- 6 months)	12 months after initiation of Nintedanib (+/- 6 months)
Date of score			
Score			

8. ADVERSE DRUG EVENTS

	YES	NO	Unknown/ not applicable	DETAILS/REASON	
Did the patient experience adverse effects of Nintedanib?	☐	☐	☐	*Specify adverse effects*	
Did the patient develop hepatotoxicity?	☐	☐	☐		
Did the patient develop GI side effects?	☐	☐	☐	*Specify GI effects*	
Did the patient require anti-diarrhoeal medication?	☐	☐	☐		
Was the dose of Nintedanib reduced?	☐	☐	☐	*Reason for change*	
				Dose change 1 (inc frequency)	*Duration on new dose*
				Dose change 2 (inc frequency)	*Duration on new dose*
Did the patient require dose reduction of other immunosuppressive therapy (e.g. MMF) to improve tolerability?	☐	☐	☐	*Specify drug and reason*	
Did the patient experience weight loss	☐	☐	☐	*Specify amount*	
Did the patient experience bleeding	☐	☐	☐	*Specify*	
Did the patient require a change in anticoagulant therapy?	☐	☐	☐	*Drug, change and reason*	
Did the patient experience angina or other evidence of ischaemic heart disease	☐	☐	☐	*Specify*	
Is the patient still on Nintedanib at 12 months	☐	☐	☐	If NO:	
				Reason for discontinuation	
				Duration of treatment (months)	

9. RESPIRATORY HOSPITALISATIONS

	12 months preceding Nintedanib initiation	12 months following Nintedanib initiation

Total number of hospital admissions with respiratory symptoms		
GP attendances with worsening of respiratory symptoms		

COVID-19 data

	Yes	No	Unknown	
Was the patient shielding during the national COVID-19 lock down?	☐	☐	☐	
Did the patient suffer from COVID-19 infection?	☐	☐	☐	IF **YES:** Clinical diagnosis ☐ Confirmed diagnosis (PCR) ☐ Confirmed diagnosis (Serology) ☐

10. ACUTE EXACERBATIONS OF ILD

	12 months preceding Nintedanib initiation	12 months following Nintedanib initiation
Total number of hospital admissions with acute exacerbations of ILD		
GP attendances with acute exacerbation of ILD		

11. SURVIVAL

	Yes	No	If **NO**:	
Is the patient alive at 12 months following nintedanib initiation	☐	☐	Cause of death	
			How long after initiation of nintedanib did patient die?	