CATALOGUE OF SERVICES

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Assistance for sponsors in development of clinical research projects

1	**Proposal of participants for an expert group and/or a scientific committee for the research**	
2	**Provision of expertise during the design of the research**	
	a	Advice on and/or drafting of scientific, conceptual, methodological and biostatistical aspects
	b	Regulatory and ethical advice
	c	Technical and operational advice
	d	Early, macroscopic estimate of the project's cost in France
3	**Critical review of research documents**	
4	**Consultation with patient association(s)/expert patients**	
	a	Listing of French and possibly foreign patient associations related to the disease and facilitating contact between them
	b	Organisation of the consultation with the association/expert patients
5	**Feasibility of the research in France (country feasibility)**	
6	**Identification of potential centres**	
	a	Proposal of a list of centres to the sponsor, based in particular on the network coordinating unit's detailed knowledge of the centres
	b	Review of a list proposed by the sponsor, based in particular on the network coordinating unit's detailed knowledge of the centres
7	**Recruitment strategy**	
	a	Identification and proposal of recruitment methods tailored to the patient pathway
	b	Assistance in putting into place the identified recruitment strategy
8	**Coordination of the "centre feasibility" study**	
	a	Creation of a feasibility questionnaire
	b	Mailing of a feasibility questionnaire and confidentiality agreement to each potential centre, centralisation of responses
	c	Analysis of responses and preparation of detailed feedback for the sponsor to assist with the pre-selection decision

Assistance for sponsors in development of real-world database and cohorts research projects

Development / review of real-world database research projects	
9	a) Identification of relevant data sources (Electronic health records, National Health Data System, Panels) b) Definition of the best methodological approach(es) (emulated trials, digital twins' cohorts, matching and adjustment processes…) c) Design of algorithms to identify patients and outcomes of interest d) Health economics modelling e) Quality insurance (compliance with recognized standards)

Development / review of real-world cohort research projects	
10	a) Definition of key research questions b) Definition of core and optional characterization sets (phenotyping, endotyping) c) Definition of core and optional outcomes sets d) Definition of recruitment strategies including interaction with patients' associations e) Identification of sites f) Definition of follow-up requirements (intervals, duration) g) Definition of monitoring rules for quality control

Assistance to the sponsor in setting up the research and supervising the centres' activities

Basic support for the conduct of the research	
11	Scoping meeting with the sponsor before the start of the research Keeping administrative documents concerning the network up to date and mailing them to the sponsor Assistance in drafting scientific responses to requests by the authorities Supervision of the centres' activities during monthly joint meetings Advice and assistance during the course of the research, in particular regarding the measures to be taken in the event of macroscopic difficulties Assistance if any difficulties are encountered with a centre

Other research-related services		
12	Assistance in organising visits/meetings during the research or in the preliminary stages	
13	Centralised collection of the documents required to initiate the centres	
14	Assistance in drawing up and signing the single agreement	
	a	**Initial** (coordinating and associated centres) - Assistance in discussions with the coordinating centre for the drafting of the SA template - Distribution of the SA template to the associated centres and exchange of information with them to limit specific additional requests - Optimisation of signature flows for all centres (in the event of paper signatures)
	b	**Amendments** (coordinating and associated centres) - Assistance in discussions with the coordinating centre for the drafting of amendments to the SA - Distribution of the amendment template to the associated centres and exchange of information with them to limit specific additional requests - Optimisation of signature flows for all centres (in the event of paper signatures) ***Note**: The processing of amendments requiring a complete revision of the SA will be invoiced as for the drafting of the initial SA*
15	Regular and specific contact to monitor the research	
16	Critical review of statistical and clinical reports	
17	Involvement in communication of the research results	

Other non-research-related services	
18	Organisation of seminars and/or training courses on the disease and its environment Partnership for dissemination of information on the disease to patients and the general public

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Network's contribution to maintaining research quality in the centres

Implementation of an oversight system for staff conducting research	
19	a) Continuing training system for staff in the field concerned by the research, on GCP *(TransCelerate programme)* and recent developments in clinical research *(including the recording and traceability of these training courses)* b) Administrative files for employees c) Transmission to the sponsor or the network's coordinating unit of administrative documents concerning the centre's staff d) Ability to mobilise resources to respond to requests from sponsors generating peaks in activity e) Guarantee continuity of activity by anticipating absences

Implementation of a quality system dedicated to conducting research	
20	a) Presence of a dedicated quality advisor at the centre to: • Manage quality at the centre • Manage internal processes, particularly concerning the conduct of research • Support the investigation teams • Identify and analyse internal non-conformities/Identify corrective and preventive actions/Monitor the impact of these actions b) Quality management of source files in accordance with the standards required for clinical research. c) Creation of supporting documents for the centre's staff based on an analysis of the research documents. d) Updating of KPIs, site authorisations (if applicable) and information sheets describing the centre (transmission to the sponsor or the network's coordinating unit according to the process in force). e) Preparation and training of the stakeholders involved in the research prior to audits or inspections.