

CENTRAL MANAGEMENT OF CLINICAL DOSSIERS

Multicentric studies require the central review of source data by independent experts such as Adjudication Committees, Review Boards, Clinical Event/Endpoint Committees and uniform procedures for handling trial-related events.

Relying on its logistical know-how, and as a complement to its core activities, **cardibase** embarked on the centralization of clinical dossiers by allocating the resources necessary to manage the communication and circulation of documents between clinical sites, central reviewers and study teams.

The critical nature of the information collected and redistributed implies strictly controlled conditions such as:

- > Confidentiality
- > Blinding control
- > Specific filing, separate from the study files
- > Re-distribution of information to designated parties
- > Close adherence to reporting time lines

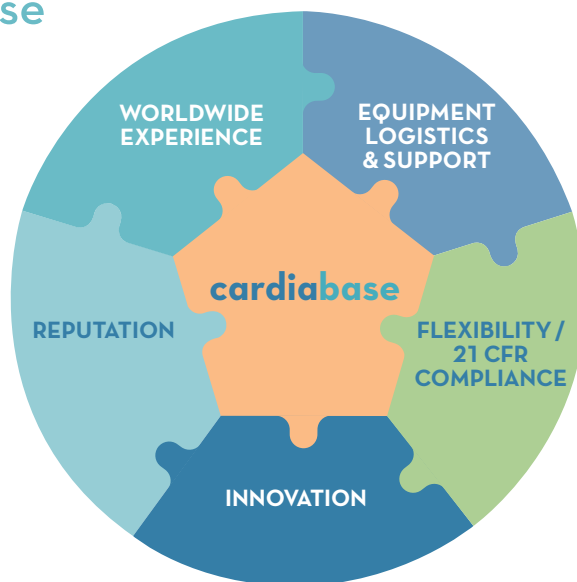


Tasks and responsibilities include

- > Design and distribution of specific documentation and forms
- > Tracking and collection of source documents from sites
- > Filing and preparation for review
- > Submission of documents to central reviewers
- > Interaction and correspondence with central reviewers including face-to-face meetings
- > Collection and processing of interpretations from central reviewers
- > Providing study-specific reports and tools

CardiaBase has appointed a dedicated team to manage these projects. All team members are well versed in logistics and have developed unique know-how.

WHY CHOOSE cardibase



KEY BENEFITS OF cardibase AS A CARDIAC SERVICES PROVIDER

- > Flexibility and service-oriented attitude
- > In-house medical, scientific and regulatory expertise
- > Capacity to absorb large volumes of data
- > Capacity to support multinational trials
- > Unparalleled experience in early phase trials
- > Stability



contacts

Pascal Voiriot, CEO

pascal.voiriot@cardibase.com

tél. + 33 3 83 39 10 10

Pierre Soumenkoff, Business Development

pierre.soumenkoff@cardibase.com

tél. + 32 2 633 33 23



cardibase

Villa Alsacienne
78, avenue du XX^e Corps
54000 Nancy | France
tél. +33 (0)3 83 39 10 10
fax +33 (0)3 83 37 36 36

www.cardibase.com