Table of terms

- CRU: Clinical Research Unit
- Sponsor: Pharmaceutical Laboratory developing and funding the clinical trial
- CRA: Clinical Research Associate, coordinator of the study within the CRU
- CRA-Coordinator: Clinical Research, study coordinator for the Sponsor
- AE, SAE: “adverse event”, “serious adverse event”, side effects gradation
- PK: Pharmacokinetic test (dynamic monitoring of the effect of the drug minutes and hours after administration)
- EDC / CRF “electronic data capture / case report forms”: Sponsor secure portal allowing the CRA to record the data from day to day clinical trial
- Kit: Equipment to be used for the test, provided by the Sponsor
- Vital Signs: Physical parameters for monitoring the patient’s general condition
- Index CTCAE: Common Terminology Criteria for Adverse Events (Internationally standardized method to describe and grade the AE and SAE)
- RECIST: Response Evaluation Criteria in Solid Tumors (internationally standardized method for measuring the evolution of tumors)
- Cohort: A group of patients in a clinical trial

Functional and technical description

1/ The benefits of the VenturaCare approach

VenturaCare suits the needs of all types of Clinical Research Units:

- For medical units in which therapeutic research remains a somewhat marginal activity, the VenturaCare software will help managing efficiently the trials with a high quality level, although the staff is not dedicated and only partially formed, with the exception of a CRA often part-time,
- For major CRU fully equipped with their own resources in terms of staff and beds, VenturaCare will allow increasing their productivity, maximizing the number of patients withing available resources, and maintaining a high level of quality for the sponsor laboratory.

1.1 A small investment to master the complexity of clinical research protocols

Mastering the precise implementation of protocols require considerable investment of CRU:

- This is the specific role of the CRAs, the direct interface of the CRA-Coordinator,
- Every protocol has a very significant impact on nursing roles, including the supply and usage of sampling kits,
- Physicians must spend a lot of time to monitor and control
- Admin/secretary team has a special role to plan and organize appointments with third actors, imposing specific constraints

VenturaCare is encoding the requirements of the protocol and provides reminders for each trial cycle and guidance on any aspect relating to the formalisms of the trial.

1.2 Minimizing differences and deviations

Any deviation, variance, loss of information, incomplete document etc. triggers a series of actions and queries at the request of the CRA-Coordinator, which are extremely time consuming and degrade the RCU reputation.

VenturaCare provides a framework to create a single comprehensive and consistent source material covering the expectations of the most formal and demanding Sponsors.

1.3 Dematerializing elements of patient records for daily use

The paper file remains the reference (source docs) but should not be used as a working tool for the daily CRU (risk of loss or mishandling, time consuming manual search, file unavailable on the spot when needed...).

VenturaCare offers a cloud approach (tablet, multiple workstations) while preserving traceability and approval mechanisms, reducing the paper editions to the strict essence of source material kept available to the CRA-Coordinator

1.4 Improve the collective response

One of the challenges of a CRU is to provide information within the Sponsor deadlines (1-5 days), so responsiveness is a key quality criterion for the CRA-Coordinator. Patient's files, trial files, tasks and resource management of the CRU shall remain transparent to insure seamless teamwork and absolute reactivity.

VenturaCare removes most of the delays in recording and sharing information. It can also automatically notify (text messages, pager, mails...) any “abnormal” event (SAE, deviations from the protocol values and parameters etc.)

1.5 Optimizing the management of resources by maximizing inclusions

VenturaCare allows optimizing the allocation of resources in all situations:

- When the inclusion limit is the access to a sufficient population of relevant patients, facilitating and accelerating the inclusion and management of a larger cohort of patients,
- When the inclusion limit is the saturation of the RCU resources, not only at the time of inclusion, but also over all treatment cycles, VenturaCare allows to highlight all potential slots for additional inclusions.

This is achieved by tabulating the cumulative workload of all active protocols (each with its specific schedule of visits, PK, examinations etc.) over any time period in terms of human and materials resources availability, including consideration of holidays and planned absences, up to reaching generalized resources saturation i.e. maximum productivity.

1.6 Automatizing specific billings RCU

The time of the physician investigator and his team is too valuable to be spent on administrative tasks with the Sponsor’s laboratory, such as billing...

A specific VenturaCare module provides automatic billing at the desired frequency (typically monthly), integrating all potentially billable acts of the on-going trials on the basis of the agreed contract-grid between the RCU and each Sponsor.

2/ Principles of Software VenturaCare

In the VenturaCare software, each protocol is defined by a series of “cycles», each one generating a chain “events», in the sliding time scale specified by the protocol and “hard coded» during the creation of the protocol.

These events are materialized in the trial agenda as soon as a patient is included. They are expressed in explicit language typology («visit», «bone scintigraphy», «Pharmacokinetic PK», etc.), and are submitted to the person in charge of the planning approval, which confirms their precise actors, date and time. They become then visible in the specific agenda for each user, and automatically mobilize the associated resources (beds, nursing time, sampling kits ...), creating alerts should any resource appear unavailable at this time in the current inventory and schedules. Complex events (eg PK) can be broken down into a sequence of sub-events in a timed chronology (eg a sequence of medications and samples). Reminders can be generated automatically (SMS, mails).

The medical record of each patient is enriched at each stage, the software offering a number of entry pages (suited to the medical path of each visit), individualized summary editions (historical combined vital signs, doses, signs of toxicity (AE, SAE) and concomitant medications, the evolution of tumors), and paper editions with formulations in accordance with the requirements of the protocol to generate the formal «source document».

A combined vision is available at protocol level (monitoring of the cohort, automatic billing), or protocol group level (vision «team»).

The management of all events «protocol» is supported by a number of automated aids to the management of the RCU «process», such as: automatic notification of AE, SAE, death, exit of protocols, modification of data defined as «source», data pending validation etc... These automated notifications are predefined to reach most expeditiously the CRA, the Principal Investigator or the whole team for this protocol, depending on the setting selected.

The VenturaCare software finally provides easy access at any time to the specifications and special requirements of each protocol, jointly managing all the information deemed useful by the CRA and PI, usually:

- The one-click access to complete reference documents (protocol itself, training documents prescribing laboratory, databases «protocols» Online ...): repository “protocol”

- The one-click access to records and other guides created by the team during the implementation of the Protocol: repository «events»
- Online help available on each page (for example, from the entry page “concomitant medications» providing a list of trade names associated with each molecule incompatible with the clinical trial)

The immediate access to the exact reference data in case of doubt is essential and an important factor for improving the trial data quality: it is well known that the drafting of a protocol is primarily guided by the desire to get the green light from the health authorities, not necessarily structured in the most convenient way for the test team of this protocol (in addition, documents are in English, treatments and molecules defined generically etc..). With the exception of protocols associated with a very large cohort, being then the only study of the project team, everyone recognizes that it is impossible to remember all the requirements for each of the protocols; these online aids are an essential condition for the success of any clinical trial.

In brief, the VenturaCare software allows managing:

- The timeline of each patient included in a protocol, from the date of his/her inclusion,
- The global dynamics of the development of a protocol, including combined trends of efficacy and toxicity,
- Creating source material fully compliant and structured data for their seamless transfer to the Sponsor without research or additional editing in the eCRF,
- Quality assurance requirements in terms of data and process.

3/ An incremental deployment and configurable

- Choice of a new protocol for migration without duplication
- Avoid double-entry, instead reduce them
- From stand-alone to integrated tool (external connectivity)
- Towards the e-CRF machine-to-machine (M2M)
- Customizable to reflect the CRU internal organization, pre-existing tools, the supplier chains internal and external

4/ A natural logic without heavy training constraints

4.1 Each player chooses its viewpoint

- Patients angle for Doctors and Nurses
- Protocol view for CRAs
- Timetable logic for planners
- CRU overall activity

4.2 A guiding role for the data collection

- Follow-up of treatment doses
- Consultations calendar management
- Examinations, nurse procedures, samples
- AE, SAE,

- Concomitant medication

4.3 A role of memory

- Historic vital signs
- Historical AE
- Medication history
- History doses of the drugs tested

4.4 A tool for resource management

- Beds
- Nurse time sheets
- Sampling kits
- Pharmacy
- External services (imaging, nuclear medicine, biopsy ...)

4.5 A tool to monitor and forecast billings

- The contract with the hospital environment
- The contract with the physician
- Monitoring of contract billing with the physician

4.6 A (future) e-CRF tool

VenturaCare is currently under negotiation with major Labs and CROs to create machine-to-Machine (M2M) interfaces between VenturaCare and the most used e-CRFs, which will spare one of the most time-consuming activities of CRAs.