Electronic Data Capture: Is there an easy way for physician initiated research?

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Physician initiated research

4-French-compatible endovascular material is safe and effective in the treatment of femoropopliteal disease: results of the 4-EVER trial.

Superiority of stent-grafts for multicenter randomized superficial femoral artery: twelve-month results from a

Carotid stenting with distal protection in high-surgical-risk patients: one-year results of the DURABILITY I study.
Bosiers M1, Deloose K, Torseillo G2,3.

Drug-eluting stents

24-Month Data from the BRAVISSIMO: A Large-Scale Prospective Registry on Iliac Stenting for TASC A & B and TASC C & D Lesions.

Abs...
Clinical Research: What is important?

- Protocol
- Patients
- Study momentum: enrollment
- **Good Clinical DATA!**
  - Improves credibility of study
  - Improves journal acceptance
What challenges face physician investigators?

- Collecting data accurately and easily
- Maintaining study quality and compliance
- Keeping within budget
- Maintaining study momentum and enthusiasm across sites
  - Impacts enrolment rates
  - Impacts quality of data collected

A good data collection tool can address many challenges!
How it was done...

Day 0
Patient visits hospital

Day 0 - 90
Continuing enrolment

Day 91
Transfer of pCRFs to DM

Day 93
Data entry 2

Day 125
Database lock

Day 1
Data entry in pCRF

Day 90
Monitoring & collection

Day 92
Data entry 1

Day 94 - 124
Data management

Day 125 - 139
Statistics
With known disadvantages

- Lost time
- Risk of entry errors
- Shipment of data
- Entering data multiple times
- Paper storage
New approach ..... technology

Immediate access to your data & 20% faster in getting your final report
FMRP selection criteria for EDC

- Easy to set up
- Easy to use for clinical sites
- Flexible in case of amendments
- Edit / validation checks in system
- Notifying e-mail when new subject is enrolled
- Create Queries
- Simple Data Extraction
- Transparent pricing: budgeting
Easy to set up – create CRF

ADD new question and customize to your own specific needs
Easy to set up – invite centers and users

ADD centers easily

ADD users with different roles
Easy to use for clinical sites

Clear overview of different subjects, visits and forms

Visit form

12 month visit performed? (Yes, No) [protocol deviation] [clear]

Visit date: 19-Jan-2016 [clear]

Any event between 6 and 12 Month FU visit? (No, Yes) [adverse event] [clear]

-please complete an adverse event form
Flexible in case of amendments

Create a new version, based on a previous one
Edit / validation checks

Add validation rules to minimize data entry errors and missing data
Notifying e-mail

New notification


Trigger this notification
- when a subject is enrolled

Select the trigger for this notification

An e-mail notification will be sent every time a new subject is enrolled in the study.
Create Queries

Simple and clear to Make Queries
Simple Data Extraction

Create reports or export full data

Create AE report

1. Select source
2. Select contents
3. Preview report

- Export to Excel
- Export to SAS
- Export Audit Trail

Study data export in Excel (csv) or SAS.

Study Audit export in Excel (csv).
Transparant pricing

Fixed prices, to allow budgeting (research grants)

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edc2go ® is a genae product: www.edc2go.com
Advantages of edc2go

- One time data entry
- Credibility of data
- Regulatory compliance
- Data availability for publications
- Source data upload
- Grant provider can have access
- Automated edit checks
- Security of the database
Conclusion

User-friendly

Very intuitive

High-quality data

Prompt study results

Very interesting price