VIVACTIS MEDTECH
HEALTH COMMUNICATIONS GROUP

WE CARE

Clinical Research & Development
Consulting & Strategy
Clinical trials
Post-Marketing Observational Studies
Market Access

www.vivactis.com

May 2016

WHAT WE DO

Clinical Research & Development

- Pre-market safety / efficacy (ISO 14155) processes
- Post marketing long-term product performance evaluation (e.g. for reimbursement)

Consulting & Strategy

- Needs analysis, adapted and realistic solutions, taking into consideration:
  1. Client's objectives (*CE marking, new indication, product re-positioning)
  2. Study feasibility
  3. Regulatory strategy
- Expert consultancy (national and international networks)
- Sponsor assistance with regulatory authority
- Partnership with specialized agency for *CE marking submission

Clinical trials & Post-Marketing Observational Studies

- Clinical trials to provide valid scientific evidence
- Post marketing, non-interventional studies
- Side-effect follow-up studies
- Studies for regulatory perspectives

Market Access - Reimbursement

- Strategic advice: market access strategies, market size evaluation
- Expert network for medico-economic analyses

* Conformité Européene/European Conformity

CASE STUDIES

CASE STUDY 1

Context

- A medtech company intends to launch a product that has already been on the market but has lost its *CE marking for various compliance issues
- The new product has been completely re-designed and is ready to be marketed
- Production and sales are at a standstill
- Lack of internal resources

Objective

- Successful *CE Mark filing
  - Produce complementary analysis about existing clinical data
  - Compile a technical file
  - Submit answers to the specific questions from the "notified body"
- Beginning of the go-to-market plan

VIVACTIS Mission Phase 1

- Advise on the *CE Mark filing and answers to the questions from the "notified body"
  - On-site monitoring of clinical data and correction of any inconsistencies
  - Long term follow-up of patients in order to confirm the product's tolerability
  - Complete overhaul of the statistical analysis
  - Technical file creation with a specialist partner
  - Close contact via the local branch (European Country)

VIVACTIS Mission Phase 2

- Assist in the product launch with the set-up of a PMCF (Post Marketing Clinical Follow-up) study
  - Carry out an international observational study
  - Integrate the study into the marketing plan
  - Creation and coordination of a KOL network (including creating a scientific Advisory Board)
  - Direct contact with targeted physicians

Results

- Increased product knowledge by targeted specialists (prescribing doctors)
- Collection of scientific data for publication
- Strengthening of the product's brand image

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Case studies by:

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CASE STUDY 2

Context

- The medical affairs director of a European, medium size, multinational, medtech company has recently resigned
- A phase IV multicentric study is ongoing, under the coordination of the company's affiliates and the supervision of the European HQ
- The product under investigation is an implantable medical device

Objective

- Fully coordinate the ongoing phase IV clinical study (250 patients)
- Conduct the data analysis and final report
- Stimulate patients recruitment

Vivactis role

- Interim study management by the Vivactis team
- Close collaboration with local coordinators
- Oversight of successful study completion

Result

- Study completed according to timeline (with fully outsourced coordination)

CASE STUDY 3

Context

- The clinical affairs department of a large, multinational medtech company is in need of support for one of their studies; the main issue is an unexpected slow down in patients recruitment
- The company mandates Vivactis for an audit of the study and to make a recommendation to correct this counter-productive trend

Objective

- Find the best solutions to boost patients recruitment

Vivactis role

- Conducted an audit (including investigators' interviews
- Proposed some cost-effective and innovative patients recruitment boosting communication solutions
- New media were favoured, given the younger category of patients in the study
- Coordinated contact with the scientific board

Result

- The negative recruitment trend was reversed and the study was completed with a very limited timeframe extension

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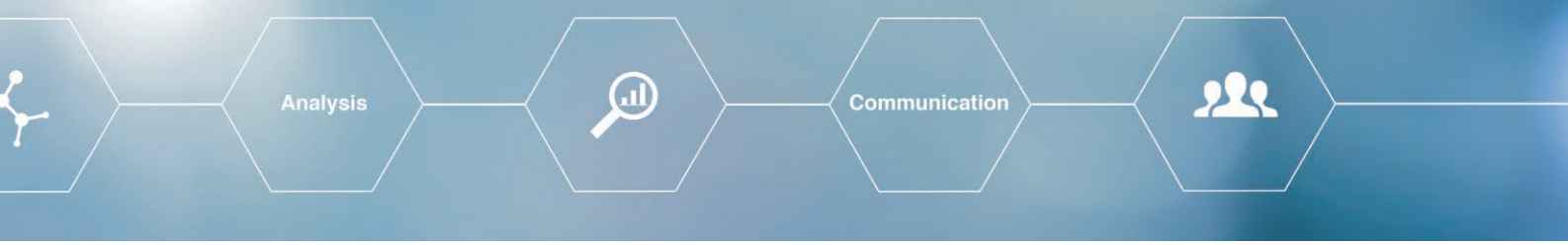

CASE STUDY 4

Context

- An eye-drops manufacturer (Medical Device of class IIb) is commercializing several products in France, without any reimbursement

Mission

- Define the type of study to conduct (non-inferiority versus the reference product)
- Manage all aspects of the study from start to completion

Objective

- Carry out a study to support the request for reimbursement

Results

- Study completed successfully with non-inferiority statistically demonstrated
- The request for reimbursement is on-going
- A second study has been requested for another product in the portfolio

CASE STUDY 5

Context

- Start-up company with an innovative Medical Device
- Currently does not have a *CE mark (Class IIa)
- Need for data in order to obtain a *CE mark

Mission

- Define the type of study to conduct
- Manage successful completion of a multicentre study in France
- Direct contact between Key Opinion Leaders and targeted physicians

Objectives

- Carry out a study in order to support the request for a *CE mark (security data), and obtain data in order to support future commercialisation

Result

- Study on-going

CASE STUDY 6

Context

- Start-up with an innovative Medical Device (a neurofeedback device for the treatment of hyperactive children)
- No *CE mark (Class IIa)
- Need for data to obtain a *CE mark

Mission

- Define the type of study to conduct
- Complete management of a multicentre study in Europe
- Direct contact between Key Opinion Leaders and targeted physicians

Objective

- Carry out a study in order to support the request for a *CE mark (security data), and obtain data in order to support future commercialisation (efficiency data)

Result

- Study on-going

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