COR2ED
THE HEART OF MEDICAL EDUCATION

NEW ADVANCES IN LIPID MANAGEMENT REQUEST FOR PROPOSALS

EDUCATING PHYSICIANS AND PATIENTS ON GENETIC TESTING TO IMPROVE THE DIAGNOSIS OF PATIENTS WITH FAMILIAL HYPERCHOLESTEROLEMIA

MAIN COLLABORATORS: COR2ED – LIPIDS AND GENETIC INTERNATIONAL EXPERTS FROM

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Educational Grant request from COR2ED GmbH Independent Medical Education Company

ABSTRACT

The **goal** is to improve the diagnosis of patients with FH by educating physicians and patients on Genetic Testing in FH, with 5 educational objectives:

1. Genetic origin of FH
2. Genetic testing and FH
3. Clinical use of Genetic Testing to screen FH patients
4. Implementation of cascade screening in clinical practice
5. Education for patients

Audience: specialists diagnosing and treating patients with FH (cardiologists and lipidologists). Additional resources will be developed to support patients and their families.

Methods: a free online CME-accredited e-learning with dissemination through IAS and its affiliate societies. Supported by educational material for patients and their families.

Assessment: within the e-learning an immediate evaluation of the participant's understanding, together with a comprehensive overview of the outcomes of the educational programme: number of participants entering, number of completions, breakdown by country, results of the assessments etc. National data on the frequency of genetic testing in FH will provide a baseline measurement.
In two or more regional centres the use of the genetic testing and the diagnosis-rate of FH will be measured over a certain period of time. All involved staff-members will be educated through the e-learning. The use of genetic testing and FH diagnosis-rate over this period will be measured.

The full comprehensive project will include needs analysis and outcomes assessment. COR2ED and the Scientific Directors are committed to obtain additional funding to conduct the scientifically valid outcomes measurement.

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ANSWERS TO IAS REVIEWER COMMENTS

The full project will be comprehensive: from the needs analysis to the set-up of a robust methodology for the assessment of the impact of the educational programme on the use of genetic testing and the diagnosis of Familial Hypercholesterolemia (FH).
This grant request covers the development of the e-learning and its dissemination to the largest possible appropriate audience, through IAS and in partnership with affiliates societies. An immediate evaluation of the participant's understanding of the educational objectives will be conducted.
In addition, dedicated educational material will be developed for patients and their families. This will be made available for HCPs to support them in the communication with patients and their families on the genetic origin of the disease.

A complementary funding source will support a robust methodology for the assessment of the impact of the educational program on the use of genetic testing and the diagnosis of FH in actual clinical practice.

GOAL & EDUCATIONAL OBJECTIVES OF THE PROGRAMME

The goal of the programme is to improve the diagnosis of patients with FH by educating physicians and patients on Genetic Testing in FH.

To achieve this goal 5 educational objectives have been identified:

6. Explanation of the genetic origin of FH
7. Genetic testing and FH: how does it work and what can we learn from the test?
8. Clinical use of Genetic Testing to screen FH patients: When and How should the test be conducted, interpretation of the results and a guidance for treatment
9. Explore the implementation of cascade screening in clinical practice
10. Improve education for patients regarding the genetic aspects of the disease to enhance compliance

The content will be adjusted to be compliant with all the rules and regulations regarding genetic testing in the USA or Europe.

NEEDS ASSESSMENT

SITUATION ANALYSIS
Across the main countries around the world less than 1% of patients with FH are diagnosed. (The few exceptions are: 71% in the Netherlands, 43% in Norway, 19% in Iceland, 13% in Switzerland, 12% in the UK, and 6% in Spain).
This under-diagnosis leads to a suboptimal treatment of patients with FH, who have a 10-fold increased risk of CHD.

In current clinical practice patients with FH are diagnosed clinically and phenotypically. The latest scientific insights regarding the genetic causality of the disease and the associated diagnosis, led to the understanding that up to 40% of patients cannot be clinically diagnosed.

These data confirm that FH is vastly under-diagnosed in most countries and an increased use of genetic testing could help to improve this situation. Genetic testing used in combination with the clinical diagnosis, cascade screening and universal screening will improve the diagnosis-rate.
Some national guidelines and recommendations around the world already encourage the use of genetic testing to diagnose patients with FH, in association with clinical diagnosis. (Such as in the UK, USA (NLA), France, Australia and New Zealand)
All of these recommendations highlight the importance for HCPs to be able to conduct an informed results analysis supported by genetic expertise and the appropriate patient information. In some countries like France it is required by law to be educated on the correct results interpretation and subsequent skills to appropriately inform patients and their families. This is mandatory for HCPs to order the genetic test. But so far no such educational programmes are available.

Genetic testing on FH should be used in routine clinical practice but requires the appropriate education for it to be used in clinical practice. As of today no educational programmes exist for HCPs to support them in this knowledge. The educational programme needs to be endorsed by a well-established professional society such as IAS, to reflect the high scientific value of the programme and encourage HCPs to use it as a guidance.

Rules and regulations about genetic testing are different in various part of the world. The educational programme will take this into consideration, tailoring and amending the content accordingly.

AUDIENCE & WORLD-RENOWNED EXPERTS

The proposed educational programme will be specifically designed to address the needs of specialists diagnosing and treating patients with FH, such as cardiologists or lipidologists. Additional resources will be developed to support patients and their families in their education.

In close collaboration with four world-renowned scientific and clinical experts (Scientific Directors), COR2ED will develop educational material to address the pre-identified educational objectives. These four international experts will have the necessary complementary expertise regarding lipids, genetics and the rules and regulations applying in Europe and the USA on genetic testing.

The expected outcomes of this programme are to improve the use of genetic testing by specialists such as cardiologists or lipidologists in order to improve the diagnosis-rate of FH beyond the current rate in each of the countries (less than 1% of patients with FH are diagnosed in most of countries, with few exceptions: 71% in the Netherlands, 43% in Norway, 19% in Iceland, 13% in Switzerland, 12% in the UK, and 6% in Spain).

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The improved diagnosis-rate will support improved disease management and should impact the outcome of patients.
Further benefit for patients from this programme is the dedicated educational material that will be developed and made available for the HCPs to support them in the communication with patients and their families on the genetic origin of the disease.

The final programme content will be owned and endorsed by the IAS. The IAS member societies will be invited to collaborate on the programme to provide their members with the opportunity to benefit from it and encourage them to use it. The IAS member societies will be offered to endorse the educational programme together with IAS and are allowed to directly promote the educational content towards their members. Early discussions have been initiated with NSFA (French Atherosclerosis Society) and the NLA (National Lipid Association).

A comprehensive approach will be implemented to ensure a maximum exposure of the educational resource towards the target audience, such as but not limited to: having the content hosted on the IAS website, promoted through the IAS newsletter, live presentation of the resources can be done during the next IAS congress. IAS member societies will be allowed to promote the programme through their websites, newsletters, national congresses, and COR2ED will promote the programme through its newsletter.

PROJECT DESIGN & METHODS

No educational resource currently exists for healthcare professionals to support them in their education on genetic testing and help them to improve the diagnosis and treatment of FH. The proposed programme allows IAS to own and endorse a free online e-learning available for all healthcare professionals around the world. This programme will be owned and endorsed by IAS and will be CME-accredited.

The proposed format is an interactive e-learning split into 5 modules designed to address the 5 pre-identified educational objectives.

1. Module 1: Explanation of the genetic origin of FH
2. Module 2: Genetic testing and FH: how does it work and what can we learn from the test?
3. Module 3: Clinical use of Genetic Testing to screen FH patients: When and How should the test be conducted, interpretation of the results and a guidance for treatment
4. Module 4: Explore the implementation of cascade screening in clinical practice
5. Module 5: Improve education for patients regarding the genetic aspects of the disease to enhance compliance

The content will be adjusted to be compliant with all the rules and regulations regarding genetic testing in the USA or Europe.

The latest technology will be used (videos, animations, voice-overs, interactive quizzes, augmented reality, validation questionnaires) to develop content that is as interactive as possible and of very high educational value.

Each module will be completed with a knowledge quiz to guarantee the understanding of each of the 5 the pre-identified educational objectives.

The programme will be accredited and CME credits will be provided to all participants together with an official certificate (CME credits will be valid in EU and USA). It is expected for this programme to be granted with 2 credits for those participants who successfully completed the programme.

The number of people who entered the programme, the number who completed the programme and the number of accreditation certificates delivered will measure the engagement of participants. Based on previous experience we expect more than 60% of the participants to complete the programme.
A system to remind HCPs via e-mail on the programme will be in place to invite participants who have not yet entered the programme, or haven't completed the programme yet.

Based on the content as developed for specialists, educational material will be developed for and tailored to the knowledge needs of patients and their families. This material will be made available for the HCPs to support them in the communication with patients and their families on the genetic origin of the disease.

EVALUATION DESIGN - OUTCOMES MEASUREMENT

The online format of this programme will provide a comprehensive overview of the outcomes of the educational programme: number of participants entering the e-learning, number of completions, breakdown by country, ratio of programme completions, results of the assessment-quizzes – and much more.
National data on the frequency of use of genetic testing in FH will provide a baseline measurement, together with a measurement of the impact of the programme when it comes to changing clinical practice.

COR2ED and the Scientific Directors suggest a scientific approach to measure the outcomes of the programme on the use of genetic testing and the diagnosis-rate of FH.
As part of the methodology two or more clinical teams in regional hospital centres will be identified. In these hospitals the use of the genetic testing and the diagnosis-rate of FH will be measured over a certain period of time (i.e. 6 months).
As a second step, all involved staff-members at these hospitals will be educated by using the e-learning programme on genetic testing to improve the diagnosis of patients with FH.
The final step will be to measure the use of genetic testing and FH diagnosis-rate over the same period of time (i.e. 6 months)

An analysis of the results will then be conducted to appropriately measure the impact of the educational programme on the frequency of use of the genetic test and the diagnosis-rate of FH.

Some additional criteria will also be explored such as the quality of the communication and education towards patients and their families, and the supported material used. Also the health economic impact will be evaluated.
At this stage it is difficult to anticipate the impact of the programme on the use of the genetic test and the rate of diagnostic but it has been estimated that an improvement of 15 to 20% will be impactful to improve the health or FH patients.

As per the request from the IAS external review panel this grant request will support the development and the implementation of the e learning. COR2ED and the Scientific Directors engage themselves to obtain additional funding to conduct the scientifically valid outcomes measurement.
The requested grant is considered to be the minimum to make the project viable and start to improve the diagnosis of patients with FH.

Methodology and results of the outcomes assessment will be submitted for scientific publication in a peer-reviewed journal to ensure a maximum exposure of the results and to encourage other HCPs who diagnose and treat patients with FH to educate themselves through the e-learning as offered by IAS.

WORK PLAN & DELIVERABLES SCHEDULE

The programme design and content development will be lead by the four Scientific Directors, we expect this will be completed in 4 months; qualified medical writers will be appointed to support the Scientific Directors in the content development and editing. It is anticipated that three rounds of review will be necessary to finalise the content.
The transformation of the scientific content into an interactive and educational format will require 2 months.
To achieve the highest level of educational impact, the latest technology will be used to develop a content that is as interactive as possible and of very high educational value, such as:

- Videos
- Animations
- Voice-overs
- Interactive quizzes
- Augmented reality
- Knowledge validation questionnaires

The educational architecture will be developed based on the expertise at COR2ED in collaboration with ELEVATE, an online academy liaised with the UMC (Universitair Medisch Centrum) in Utrecht (The Netherlands). ELEVATE masters the highest expertise in online training architecture.

Based on the content as developed for specialists, educational material will be developed for and tailored to the knowledge needs of patients and their families. This material will be made available for the HCPs to support them in the communication with patients and their families on the genetic origin of the disease.

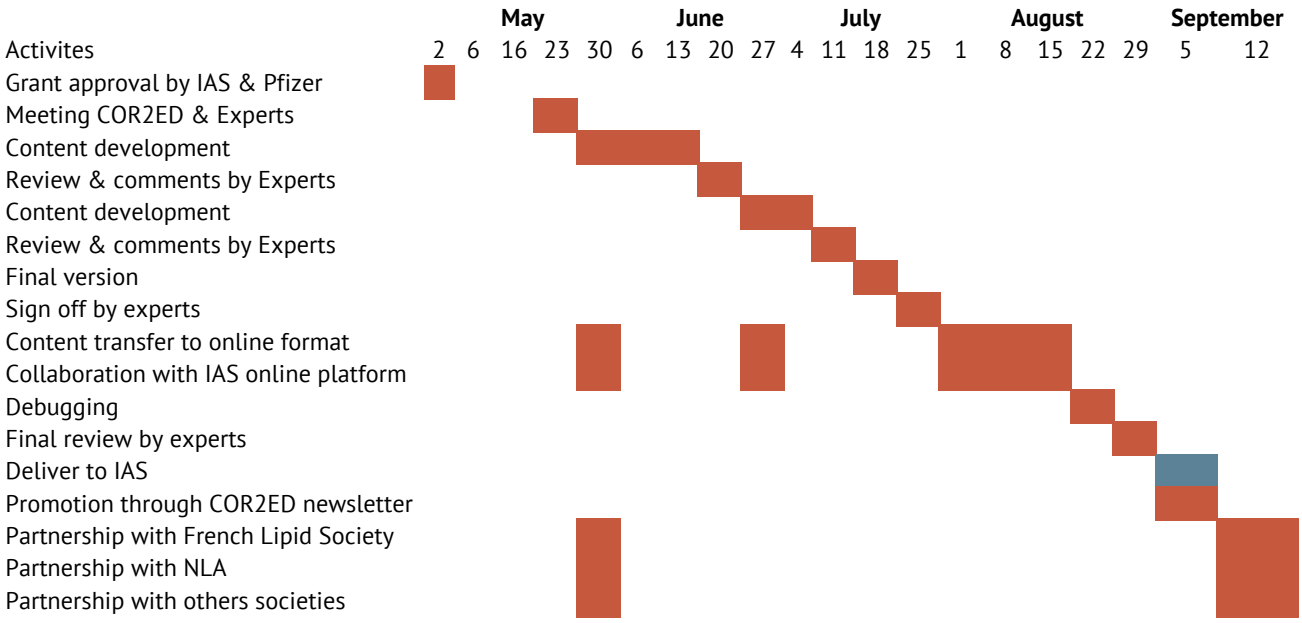
During the content development phase, the partnerships and collaborations with the IAS member societies will be initiated and set-up.

Once the content is finalised and approved by the Scientific Directors the promotion phase will start and will be pursued for at least 12 months by all the partners (IAS, IAS Member Societies and COR2ED)

Total estimated time for the programme is 5 months for content development and 12 months for promotion.

The search for additional funding to support the outcomes measurement programme will start as soon as the first grant has been approved by the IAS external review panel to allow the assessment programme to start as soon as possible after the e-learning has been finalised and approved.

WORK PLAN & DELIVERABLES SCHEDULE



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