

# Accreditation and Certification in Europe on Biomedical and Health Informatics as provided by EFMI

John Mantas

*School of Health Sciences, National and Kapodistrian University of Athens, Athens, Greece*

e-mail: [jmantas@nurs.uoa.gr](mailto:jmantas@nurs.uoa.gr)

*Abstract:* The AC2 Committee was funded by EFMI (European Federation for Medical Informatics) in order to create and suitably modify a database of educational programs across Europe since study programs in the vast fields of Biomedical and Health Informatics, Medical Informatics and Health Technology is continuously growing during the recent years. This initiative aims at the creation of an on-line catalogue that would provide information about European programs and courses in Biomedical and Health Informatics in order to support the promotion and provision awareness of the educational initiative to the wider biomedical and health informatics community in Europe and worldwide. A great variety of curricula with specialization in Biomedical and Health Informatics (BMHI), Medical Informatics, Medical Engineering and Biomedical Engineering at European Universities are offered at any academic level. For this reason, the AC2 Accreditation and Certification initiative is supported by EFMI to find and present all necessary elements in appropriate way in order to implement the Accreditation and Certification process on education in biomedical informatics, health informatics, medical informatics and the other related fields in Europe.

*Keywords:* EFMI; Biomedical and Health Informatics; educational programs; Accreditation and Certification process

## Introduction

### Accreditation

*Rationale.* Accreditation is a diligent evaluation and monitoring peer review process assuring that educational programs and institutions meet academic standards and operational integrity and quality. There is a great number of European Universities and Institutions implementing and having established programs (undergraduate and postgraduate) in the field of Biomedical and Health Informatics. A mechanism should be applied by EFMI to accredit those programs, since EFMI is the European scientific body of Biomedical and Health Informatics, where all national associations have joined in our Federation (EFMI). This accreditation will provide European added value to the programs, be supportive of cross-national mobility and be complimentary to the required national accreditations processes.

## Certification

*Rationale.* Certification is a credentialing process that demonstrates and honor qualifications that an individual can perform a specific professional role or set of tasks. Certification in Health Informatics is a requirement for many professionals in many clinical institutions in a number of countries. Specifically, Clinical Health Informatics is a special concern, as many professionals who are using or implementing health information systems or applications or instrumentation in their professional life. Even those professionals having acquired earlier degrees in Health Informatics or in related fields is required to update and certify their current knowledge and skills. Therefore, eligibility and content requirements combining 1) *Clinical practice focus*, 2) *Education*, and 3) *Significant experience* in real-world health informatics accomplishment is urgently needed to ensure qualified expertise and develop “best practices”. EFMI as the scientific federation in this discipline has the obligation to offer certification processes and certify the professionals of the current skills in the field of Biomedical and Health Informatics.

Actions for Accreditation required:

1. Accreditation standard operating procedures defined.
2. Accreditation evaluation rules defined.
3. Site-visit experts catalogue should be prepared based on eligibility criteria.
4. Accreditation secretariat should be established as mentioned above.
5. Logistical support required
6. Clear rules of engagement should be defined ensuring transparency and equality.

Actions for Certification required:

1. Certification standard operating procedures should be defined.
2. Certification task forces to be established to develop certification interprofessional program for health informatics, in sub-disciplines, and in any other required specific applications.
3. Secretariat should monitor diligently the process ensuring transparency and equality.
4. Secretariat to be established to support the process throughout all stages.
5. Logistical support clearly defined.
6. Clear rules of engagement to be defined.

## SWOT Analysis

### A. Strengths

EFMI is a European federation of national associations situated in most European countries. The scientific and professional community of Biomedical and Health Informatics is reflected in EFMI as it is yearly depicted in the MIE Conferences.

### B. Opportunities

Very few Universities/Institutions with programs in the field of Health Informatics have been accredited by an International organization. Similar initiatives had little effect in Europe. In addition, no Certification programs have been established yet in Europe in our field.

### C. Weaknesses

EFMI is a volunteer organization without solid professional secretariat support. Also, decisions are delayed due to the internal procedures. Clear mandates should be given to the Accreditation and Certification Committee to ensure minimization of bureaucracy leading to delays in implementation and decisions taken.

### D. Threats

Other international organizations, some of them, more professional ones than EFMI, have initiated similar actions and they may apply them in Europe very soon.

## Implementation of accreditation

The EFMI AC2 Accreditation assessment process is based on well-established assessment processes applied in most European countries. The EFMI Accreditation does not replace any National Accreditation required by the law in each country. It is a complimentary Accreditation judged by a peer-review process in a collegiate way assisting and supporting to achieve high quality educational programs in the field of Biomedical and Health Informatics.

The Assessment consists of five criteria. For each criterion there are several norms required to be met, therefore, facilitating the assessment.

The criteria are based on the Dublin descriptors (see Appendix A), as they have been presented and applied at all academic levels (Bachelor, Master, and Doctoral degrees)

The criteria are the following:

1. Needs and relevance
2. Intended learning outcomes
3. Academic/Teaching-learning environment
4. Organization and implementation
5. Internal quality assurance and development

All criteria should be judged by the site visit panel as either satisfactory or unsatisfactory.

If all five (5) criteria are judged by the site-visit panel as satisfactory, then the result is positive. Therefore, the final decision by the EFMI AC2 Committee is to grant the EFMI Accreditation to the program. The duration of the EFMI Accreditation of the Program is three (3) years from the time of the endorsement by the EFMI Board. A re-accreditation process is required at the end of this period.

On the other hand, if one (1) of the five (5) criteria is judged by the site-visit panel as unsatisfactory then a partial EFMI Accreditation is granted for a limited time (one year) until the applicant remedies this criterion, and the site-visit panel approves the remedy. Then the AC2 Committee grants the EFMI Accreditation as mentioned above.

If more than two (2) criteria are judged by the site-visit panel as unsatisfactory, then no Accreditation is granted, and the applicant may re-apply after at least one year when there is a proof of implementation of the major changes required.

The main document requested by the EFMI AC2 Committee from the applicant that facilitates the site-visit panel is the self-assessment report. The self-assessment report should be able to present and address the five above-mentioned criteria, starting with the presentation of the Institution, the needs in establishing and implementing such a program, and detailing the curriculum development process, the implementation, the faculty background and tasks assigned, internal reviewing, quality assurance, judgement on achieving targets and learning outcomes, students, alumni and stakeholders involvement at all stages of establishing, evaluating and quality assurance of the program. In particular, the self-assessment report should also address the required involvement of international standards and recommendations in the field of education in Biomedical and Health informatics.

## Site-visit panel members' code of conduct

### Preparation and procedure

1. The AC2 Committee appoints a 3 members site-visit panel of experienced colleagues, members of the EFMI Council, preferably with academic professional background at a level of Professorship.
2. The AC2 Committee appoints one of the 3 members as chair of the panel, responsible for coordinating the activities at a local level at the site-visit based on the assessment framework. The chair is responsible in preparing the report, contacting the AC2 committee, and addressing on behalf of the panel the hierarchy of the program under the accreditation process.
3. The panel members thoroughly prepare for the preliminary meeting and the site visit by studying all the relevant documents and responding to the proposed visit schedule.
4. The panel members base their assessment on the applicable assessment framework and act along the lines of this framework.
5. The chair draws up a draft report in accordance with the applicable assessment framework, factoring in the panel's judgements. The panel members respond to the draft report.
6. All panel members examine and endorse the report. Subsequently, the report is signed by the panel chair.

### Independence and confidentiality

1. The panel members have no affiliations with the institution / program to be assessed.
2. The panel members have the right to inspect all the relevant documents and visit specific locations.
3. Wherever confidentiality is called for, all panel members will deal with documents made available and information regarding the institution / program in a confidential manner.
4. In its declaration of independence and confidentiality, the panel commits to confidentiality in dealing with the data it has been provided with.
5. Following the assessment process, the chair will inform the AC2 Committee regarding their findings during the assessment.

6. During the assessment process, the chair and the panel members will not provide any information to the program / institution regarding their findings during the assessment, other than the feedback provided by the chair at the end of the visit or in the assessment report.

### Professional attitude

1. The panel members respect the identity and the nature of the institution / program.
2. The panel members adopt a businesslike yet open and approachable attitude. A pleasant and relaxed atmosphere is conducive to the outcomes of the visit.
3. The way the questions are presented and the subjects to be addressed will be geared to the discussion partners. Lengthy introductions will be avoided; the questions will be open-ended and preferably short. Some measure of tenacity through in-depth questions is desirable; however, within reason.
4. The documentation to be requested will be limited to what is essential. Administrative inconvenience for the institution / program will be avoided.
5. The panel members operate with maximum objectivity, impartiality, and factuality. They will refrain from voicing their own opinions in their meetings with the institution / program. Each panel member's individual views are subordinate to the panel's common view.
6. The panel members will operate in a conscientious manner; they will distinguish between desirability and reality; they will consult multiple sources and substantiate deviations. They will refrain from jumping to conclusions.
7. The panel members have an eye for both the strengths and the points for attention of the institution / program. These are identified in the assessment report. However, a structural provision of recommendations or solutions to the institution / program will be avoided.

### Attitude within the panel

1. The chair and the panel members are open to feedback.
2. All interactions within the panel will be conducted with respect to each other's contributions.

## Template of the self-assessment report

Preface

Introduction

Criterion 1. Needs and relevance

- Social context, developments in Biomedical and Health Informatics (BMHI) and the position of the BMHI program
- Similar programs existing in the region/country
- Relative needs in hospitals, in local companies, SMEs, and industries

Criterion 2.: Intended learning outcomes

- Description of the Intended learning outcomes of the program
- Links to international standards of the discipline
- Requirements of the professional field

Criterion 3. The academic/teaching learning environment

- Vision on teaching and learning
- Structure of the curriculum
- Curriculum of the program
- Embedding of the program in the clinical and research environment of the University
- The staff and its qualifications
- e-learning approaches

Criterion 4. Organization and implementation

- Vision on Organization and Implementation
- Feasibility of the program
- Regulations on enrolment and intake
- Workload and student mentoring, progress, and support
- Laboratories teaching and infrastructure
- Digital libraries
- Transparency before and after examinations
- Mentoring and supervision
- Dissertation preparation, writing, and defense

Criterion 5. Internal quality assurance and development

- Vision on quality assurance
- Student involvement and satisfaction
- Consistency, validity, and reliability of the assessment
- Assessment of skills acquired
- Evaluating achieved learning outcomes
- Conforming with international educational standards/recommendations in the BMHI field
- Quality policy and monitoring
- Careers monitoring
- Strengths and weaknesses
- Improvements

## Preparatory work by the applicant

The applicant (Director of the program) receives a letter by the EFMI AC2 Chair stating:

*“I would like to inform you that the EFMI AC2 Committee has accepted to proceed immediately as you have requested with the Accreditation procedure of your new Program at UMIT. Please find attached the documentation which is useful to prepare the self-assessment report regarding your University and the Program to be evaluated for possible Accreditation.*

*You need to prepare the following material, which should be available in a cloud server, and procedures due to the virtual site-visit:*

1. *Prepare the self-assessment report (assessment process and template attached) and send it to my address ([john.mantas@outlook.com](mailto:john.mantas@outlook.com)), and upload a copy of it at a cloud server. Please send us the appropriate link. It should be uploaded at least one week before the site visit date.*

2. *Prepare supporting electronic material, leaflets, etc. related to your University and the Program, and upload them to the cloud server.*
3. *Prepare a video demonstrating the infrastructure available for the Program, such as, auditorium, classes, laboratories, library, digital facilities, study rooms, etc. Please upload it to the cloud server.*
4. *Organize, for the day of the virtual visit, meetings with your hierarchy, preferably, Dean or Head of Department, Program Director, Labs Directors, Faculty, Alumni (of similar programs within the School), Students (of similar programs within the School), liaisons with clinics or hospitals or authorities, stakeholders.*
5. *Prepare a draft agenda of the entire meeting (pay attention to the fixed time items, such as meeting with Dean or Head of Dept, etc.). Final agenda will be issued after mutual agreement. Agenda to be uploaded to the cloud server.*
6. *Prepare the virtual teleconferencing platform with technical support to the site visit members (a prior testing with the members of the site-visit panel is recommended). Ease of use and minimum technical expertise for the platform is recommended.*

*In the next days, we will send you the names of the three members of the site-visit panel. In case, you choose that one or more of the panelists are not acceptable to your Institution due to any reason including conflict of interest, we will replace the member or the members in strict confidence.*

*We have noted your suggested dates and we will select one, accordingly.*

*We are recommending that you communicate this message to the UMIT's hierarchy indicating the initiation of the EFMI Accreditation process.*

*Please do not hesitate to send me any question you may have regarding the procedure.”*

## **Result of the evaluation based on the criteria**

In response to your letter-request for Accreditation of the Master's program in Medical Informatics sent on June 2020, EFMI started the procedures established by AC2, the Accreditation Committee of EFMI.

The AC2 site-visit panel for the Accreditation of UMIT's Master's in Medical Informatics: Prof. univ. dr. ing. Lăcrămioara Stoicu-Tivadar, Emeritus Prof. Arie Hasman, and Assoc. Prof. Inge Madsen met the UMIT faculty staff and collaborators during the one-day virtual visit on 20.07.2020.

We are glad to inform you that the site-visit panel Report was accepted by the AC2 Committee and the EFMI Board endorsed this decision on 31.08.2020. The decision states:

*“The European Federation of Medical Informatics is granting the EFMI accreditation to the UMIT's program “Master's degree in Medical Informatics” for a duration of 3 years.”*

## Conclusions

The EFMI AC2 has already initiated the procedure and the first applicant was UMIT in Austria. The accreditation to UMIT was awarded during the opening session of MIE2021 in Athens. EFMI has received new applications and we will be happy to report on the implementation accreditation process in next issues of the Bulletin.