



HEALINT4ALL



HEALINT4ALL PROTOCOL

Requirements for traineeship providers
in medical and healthcare sector

TECHNICAL FICHE

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INTRODUCTION

In medical and healthcare under the governance of professional regulatory bodies, clinical practice of trainees is an essential part of national system of Medical and Allied Health Professions (AHP) curricula. It is expected that professionals in the medical and healthcare sector have developed the expertise and experiences as required to commence their professional practice. Simultaneously, mobility of healthcare professionals is vital in ensuring a sufficient pool of qualified workforce available to deliver healthcare provision objectives. Therefore, it is of importance to initiate a quality assurance system to standardise the way medical and healthcare professionals receive the training they require, thus promoting the integration of the workforce in the medical and healthcare professional community.

This document is an output of HEALINT4ALL, an ERASMUS+ strategic partnership in higher education, whose mission is to facilitate the international mobility of trainees, and consequently, of professionals in the medical and healthcare sector to increase the supply and quality of national and international placements offered by hospitals and related medical and healthcare organizations throughout Europe. The HEALINT4ALL project provides medical and AHP education an audit system to facilitate quality assurance of European and international clinical learning environments.

The intent of this document is, therefore, to provide a set of requirements that support higher education and medical and healthcare institutions to offer and direct high-quality cross-border traineeships and simplify the processes involved in organizing these for trainees through embedding and exploiting tools across Europe and beyond.

This document uses the below four verbs with the following intentions:

- Used in requirements:

Shall indicates an obligation.

Should indicates a recommendation.

- Used in notes:

May indicates a permission.

Can indicates a possibility.

→ 1. SCOPE

This document specifies requirements for operational practices when a traineeship host organization wishes to demonstrate its ability to consistently provide and improve traineeship placements that meet the requirements of the educational organizations as well as the applicable legal requirements.

All the requirements of this document are intended to be applicable to any traineeship host organization, regardless of its type, size or the healthcare services provided.

→ 2. NORMATIVE REFERENCES

This document has no normative references.

→ 3. TERMS AND DEFINITIONS

Across this document, the following terms are used with the following technical definitions:

→ 3.1 Compliance obligations (preferred term) legal requirements and other requirements (admitted term)

Legal requirements that an organization has to comply with, and other requirements that an organization has to, or chooses to, comply with.

ⓘ Note: Compliance obligations can arise from mandatory requirements, such as applicable laws and regulations, or voluntary commitments, such as organizational and industry standards, contractual relationships, codes of practice and agreements with community groups or non-governmental organizations.

🔗 [Source: Adapted from ISO 14001:2015 Environmental management – Requirements – Note 1 to entry was deleted and Note 2 to entry was kept without numbering]

→ 3.2 Documented information

Information required to be controlled and maintained by an organization and the medium on which it is contained.

ⓘ Note 1: Documented information can be in any format and media, and from any source.

ⓘ Note 2: Documented information can refer to:

- the management system, including related processes;

- information created in order for the organization to operate (documentation);
- evidence of results achieved (records).

🔗 [Source: ISO/IEC Directives, Part 1 – Consolidated ISO Supplement – Procedures specific to ISO – Annex SL – Proposals for management system standards – Appendix 2 – High level structure, identical core text, common terms and core definitions]

→ 3.3 Formal education

Education that is institutionalised, intentional and planned through public organizations and recognised private bodies, and – in their totality – constitute the formal education system of a country. Formal education programmes are thus recognised as such by the relevant national education or equivalent authorities, e.g. any other institution in cooperation with the national or sub-national education authorities. Formal education consists mostly of initial education. Vocational education, special needs education and some parts of adult education are often recognised as being part of the formal education system.

ⓘ Note to entry: Institutionalised education occurs when an organization provides structured educational arrangements, such as student-teacher relationships and/or interactions, that are specially designed for education and learning.

🔗 [Source: ISCED]

→ 3.4 Human resources

People working within or contributing to the organization.

🔗 [Source: ISO 30400:2016 Human resource management -- Vocabulary]

→ 3.5 Infrastructure

System of facilities, equipment and services needed for the operation of an organization.

🔗 [Source: ISO 9000:2015 Quality management – Fundamentals and vocabulary]

→ 3.6 Interested party

Person or organization that can affect, be affected by, or perceive itself to be affected by a decision or activity

ⓘ Note: Examples of interested parties are: Customers, owners, people in an organization, providers, bankers, regulators, unions, partners or society that can include competitors or opposing pressure groups.

🔗 [Source: ISO/IEC Directives, Part 1 – Consolidated ISO Supplement – Procedures specific to ISO – Annex SL – Proposals for management system standards – Appendix 2 – High level structure, identical core text, common terms and core definitions]

→ 3.7 Learning environment

Physical or virtual environment in support of a learner.

🔗 [Source: ISO/IEC 2382-36:2019 Information technology – Vocabulary – Part 36: Learning, education and training]

→ 3.8 Mentor

Person(s) primarily concerned with the learning development of the trainee during the time they are within the traineeship.

ⓘ Note 1: depending on the context, there might be one or more mentors per trainee – e.g. academic mentor, clinical mentor, among others.

ⓘ Note 2: Depending on the context/culture, a mentor may be called a practice supervisor, a director, or any other job role' name which responsibilities match the above definition.

→ 3.9 Nonconformity (preferred term) incident (admitted term)

Non-fulfilment of a requirement.

🔗 [Source: Adapted from ISO/IEC Directives, Part 1 – Consolidated ISO Supplement – Procedures specific to ISO – Annex SL – Proposals for management system standards – Appendix 2 – High level structure, identical core text, common terms and core definitions]

→ 3.10 Organization

Person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives.

🔗 [Source: ISO/IEC Directives, Part 1 – Consolidated ISO Supplement – Procedures specific to ISO – Annex SL – Proposals for management system standards – Appendix 2 – High level structure, identical core text, common terms and core definitions]

→ 3.11 Organizational culture

Values, beliefs and practices that influence the conduct and behaviour of people and organizations.

🔗 [Source: Adapted from ISO 30400:2016 Human resource management – Vocabulary / ISO 30401:2018 Knowledge management systems -- Requirements]

→ 3.12 Organizational mission

Reason for being, mandate and scope of an organization, translated into the context in which it operates.

🔗 [Source: Adapted from ISO 21001:2018 – Educational organizations – Managements systems for educational Organizations – Requirements with guidance for use]

→ 3.13 Organizational policy

Intentions and direction of an organization as formally expressed by its top management.

- 🔗 [Source: ISO/IEC Directives, Part 1 – Consolidated ISO Supplement – Procedures specific to ISO – Annex SL – Proposals for management system standards – Appendix 2 – High level structure, identical core text, common terms and core definitions]

→ 3.14 Organizational vision

Aspirations of an organization in relation to its desired future condition and duly aligned with its mission.

- 🔗 [Source: Adapted from ISO 21001:2018 – Educational organizations – Managements systems for educational Organizations – Requirements with guidance for use]

→ 3.15 Risk

Effect of uncertainty.

- ⓘ Note 1: An effect is a deviation from the expected – positive or negative.
- ⓘ Note 2: Uncertainty is the state, even partial, of deficiency of information related to, understanding or knowledge of an event, its consequence, or likelihood.
- ⓘ Note 3: Risk is often characterized by reference to potential events and consequences, or a combination of these.
- ⓘ Note 4: Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated likelihood of occurrence.
- ⓘ Note 5 to entry: The word “risk” is sometimes used when there is the possibility of only negative consequences.

- 🔗 [Source: ISO/IEC Directives, Part 1 – Consolidated ISO Supplement – Procedures specific to ISO – Annex SL – Proposals for management system standards – Appendix 2 – High level structure, identical core text, common terms and core definitions]

→ 3.16 Traineeship (preferred term) apprenticeship (admitted term)

Learning that alternates between a workplace and an education or training institution; that is part of formal education and training; and that on successful completion, learners acquire a qualification and receive an officially recognized certificate.

- 🔗 (Source: Adapted from CEDEFOP)

→ 3.17 Traineeship host organization

Organization offering the traineeship placement.

- ⓘ Note: The host organization can differ in substantially according to the services offered (hospital, clinic, care home, hospice, etc.); their financial nature (public, private, etc.) and their size (micro, small or large), among other characteristics.

→ 4. GOVERNANCE

Across this document, the following terms are used with the following technical definitions:

→ 4.1 Mission and vision

The traineeship host organization shall identify its mission, determine its vision and maintain it as documented information.

→ 4.2 Organizational culture

The traineeship host organization shall identify, implement and maintain a culture that demonstrates the organization's knowledge of service users' needs and expectations and reflects cultural sensitivity, effective practice and continual improvement.

When identifying this culture, the traineeship host organization should consider:

- - anti-discrimination;
 - cultural integration;
 - a positive working attitude;
 - data protection;
 - ethical practice;
 - occupational health and safety;
 - dedication to healthcare professional development;
 - promotion and use of evidenced-based practice;
 - commitment to continuous improvement based on best practice and reflections on lessons learned.

- ⓘ Note 1: Cultural integration can include the recognition, respect and fulfilment of cultural and language needs of service users as appropriate.

- ⓘ Note 2: A positive working attitude can include sensitivity of all cultures; mutual respect; empathy; compassion; motivation; confidence; patient safety.

→ 4.3 Organizational Policy

The traineeship host organization shall establish, implement and periodically review an organizational policy that reflects the organizational culture, through a set of organizational commitments.

The organizational policy should be maintained as documented information and be available to interested parties.

→ 4.4 Compliance obligations

The traineeship host organization shall identify the applicable local, regional, national and European requirements for delivery of safe and effective care, considering:

- clinical practice;
- data protection;
- occupational health and safety;
- appropriate insurance arrangements to protect patients and their carers, employees, visitors and students/trainees in the workplace.

The traineeship host organization shall maintain documented information of the identification of the above requirements and retain documented information that the compliance has been verified.

ⓘ Note 1: Local, regional, national and European requirements can be stated in proprietary or formal standards, policies, procedures and other similar technical documents.

ⓘ Note 2: Verification of compliance obligations can be performed through self-assessment practices such as internal audits, an inspection from a regulatory body or an audit from an accredited certification body.

→ 4.5 Risk management

The traineeship host organization shall adopt a methodology for risk management related to the traineeship placements, which enables:

- identification of risks;
- evaluation of risks;
- determination of actions to address relevant risks;
- evaluation of the effectiveness of the actions implemented.

The traineeship host organization shall ensure its staff is adequately trained in the adopted risk management methodology.

Documented information regarding the adopted risk management methodology and evidence of its implementation shall be maintained and retained, respectively.

→ 4.6 Control of nonconformities

The traineeship host organization shall establish a methodology to deal with nonconformities related to the traineeship placements, which enables:

- description of the nonconformity;
- root cause investigation;
- determination of appropriate actions to address the nonconformity, the responsible persons for its implementation and deadlines;
- evaluation of the effectiveness of the actions implemented.

Documented information regarding the methodology and evidence of its implementation shall be maintained and retained, respectively and communicated to the educational organization without undue delay.

- ⓘ Note: Appropriate actions to address nonconformities can include any corrections and support measures needed as well as any actions to avoid nonconformities recurrence.

→ 5. RESOURCES

→ 5.1 Human resources

The traineeship host organization shall determine, provide and manage human resources for the traineeship placement, including:

- adequate staffing ratios and skills;
- ensuring clear job descriptions;
- support for staff life-long learning and career development.

→ 5.2 Infrastructure

The traineeship host organization shall determine, provide and maintain an adequate infrastructure that supports its organizational culture for the traineeship placement.

- ⓘ Note: Examples of an adequate infrastructure can include equipment and resources for clinical learning, personal protective equipment (PPE), hygiene resources, safe and comfortable working and resting areas.

→ 5.3 Financial resources

The traineeship host organization shall determine, provide and maintain sufficient financial resources to allow:

- conformity with the requirements of 5.1 and 5.2;
- continuous development of the healthcare services provided.

→ 5.4 Documented Information

The organizational scope in which this protocol is implemented, as well as justifications for any non-applicable requirements, shall be maintained as documented information.

To the extent necessary to enable the educational organization to recognize the traineeship, the host organization shall also:

- maintain documented information to support the operation of the traineeship placements offered;
- retain documented information, during the traineeship, to have confidence that the traineeship placements are being carried out as planned;
- transfer retained documented information to the educational organization after the end of the traineeship.

Documented information maintained and retained shall be easily available to staff, students and representatives of the educational organization, as appropriate.

① Note 1: Examples of documented information maintained can be: Induction plans, placement desired learning outcomes, documented job descriptions, health and safety documented procedures, among others.

① Note 2: Examples of documented information retained can be: Staff rotation records, insurance records, attendance records, number of hours of the traineeship, among others.

→ 6. TRAINEESHIP PLANNING AND CONTROL

→ 6.1 Onboarding of trainees

→ 6.1.1 Traineeship learning outcomes

When applicable, learning outcomes to the learning experience shall be agreed between the educational organization and the placement provider, prior to the starting date of the traineeship.

→ 6.1.2 Allocation of trainees to traineeship placements

The traineeship host organization shall assure the requirements for the traineeship placement are defined and that the trainee meets those requirements before starting the traineeship.

When the selected trainee does not meet a given requirement, the traineeship host organization shall make sure adequate actions are implemented that lead to the acquisition of the required competences during the induction phase of the traineeship.

The traineeship placement requirements, as well as evidence that the trainee meets them shall be maintained and retained, respectively.

- ⓘ Note: Examples of requirements not usually met in advance by a trainee can include competences related to specific procedures of the organization (e.g. health and safety, security) or to specific resources (e.g. medical devices, software applications or other equipment), among others

→ 6.1.3 Induction of trainees

The role of the trainee shall be identified as supernumerary, and the scope and scale of clinical procedures or interventions shall be identified and clarified for each placement location.

Orientation and induction shall be planned to address arrangements and role expectations per each placement location.

→ 6.2 Mentorship

→ 6.2.1 Assignment of mentors

The traineeship host organization shall assign a competent mentor to each trainee and ensure support to trainees in case of mentor's leave, absence, or high workload.

The identification and contacts of the assigned mentor shall be retained as documented information and made available to the trainee and hers/his educational organization.

→ 6.2.2 Mentorship competence

Mentors shall be adequately prepared to support the professional development of trainees in their placement. This shall include:

- pedagogical competence to mentor the trainee;
- professional qualification adequate to the characteristics of the traineeship;
- knowledge of relevant information regarding the traineeship, including characteristics of the placement and of the trainee allocated to it;
- when applicable, specific mentorship competence requirements related to each learning experience shall be determined.

The traineeship host organization shall assure mentor's competence is kept up-to-date.

- ⓘ Note: A learning experience can be the whole placement or a part of it.

→ 6.2.3 Mentorship responsibilities

The mentors shall be responsible for:

- the oversight of the learning experience;
- maintaining socialisation and integration within the placement team and area.

→ 6.2.4 Mentorship contact time

When mentorship contact time is mandatory, the minimum number of hours shall be determined and its distribution across the duration of the traineeship shall be planned and retained as documented information.

→ 6.2.5 Mentorship recognition

The traineeship host organization should recognize the mentors for their mentorship work.

When recognition processes are implemented, the traineeship host organization shall:

- maintain documented information on its characteristics;
- retain documented information of any recognitions attributed.

① Note: Recognition can take different formats. Examples: Money, time-off, discount coupons, promotions, certificates of recognition, revalidation of professional license/registration, etc.

→ 6.4 Learning environment

The traineeship host organization shall determine, provide and maintain a supportive learning environment for the traineeship placement, including an organizational behaviour which reflects the commitments expressed in the organizational policy (see 4.3).

The traineeship host organization shall assure the availability of a learning environment where:

- the learning opportunities match the learning objectives and level of the trainee and any exceptions justified;
- the trainee experiences the delivery of patient care based on contemporary evidence-based practice;
- there is a positive clinical learning culture which embraces and supports diversity;
- the trainee is not included in the work force and the mentor remains accountable for the trainee activity;
- there is a known system in place with specified channels for trainees and mentors to provide feedback, including concerns, complaints and suggestions for improvement;
- the role and responsibilities of the trainee are clearly identified;
- the wellbeing of the trainee is supported
- the trainee has access to relevant documented information;
- trainee feedback is used for continuous improvement of the traineeship placement.

① Note 1: Examples of embracing and supporting diversity can include:

- support acclimatization to new cultures;
- the implementation of plans to address language barriers such as translation of common medical and healthcare terms;

- the use of transcultural nonverbal communication to establish professional relationships with patients and others.

① Note 2: Concerns raised can include those related to the trainees' experience or care provided to service users;

① Note 3: Examples of relevant documented information can include policies, procedures and guidance, among others.

→ 6.5 Assessment of learning

The traineeship host organization shall assure coordination with the higher education institution regarding the assessment of learning of the trainees and retain documented information of any relevant communications held.

① Note: Coordination regarding assessment of learning may include:

- instruments used and its grading system;
- moments in which the assessment occurs;
- system to support and assist student by giving continuous feedback on student's commitment;
- system to support and recover failing students.

→ 7. ESTABLISHMENT OF PARTNERSHIPS

The traineeship host organization shall establish a partnership with an education organization that enables continued cooperation and support regarding the traineeship.

The partnership shall ensure:

- a responsible teacher is nominated for the traineeship and her/his direct contact details are available;
- the education organization is aware of the host organization's culture (see 4.2) and commits to facilitate students' compliance to the culture;
- clear insurance arrangements (see 4.4 d);
- Specific pre-requirements necessary for undertaking the traineeships shall be identified and communicated in advance.

Documented information shall be retained as evidence of the partnership, of the pre-requirements mentioned in bullet d) above and of any other relevant communication regarding the traineeships hosted.

① Note 1: Examples of pre-requirements can include visas; health precautions (e.g. vaccinations), criminal records; language requirements; preparatory courses; etc.

① Note 2: A partnership can be evidenced through a documented agreement describing the rights and obligations of the parties involved.

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