

Instructions on how to fill in the Annex: IHI Type of Participants

Introduction

The Innovative Health Initiative Joint Undertaking (IHI JU) aims to enable the cross-sectoral integration of technologies, know-how, products, services, and workflows for people-centred healthcare.

In order to capture this integration, the IHI JU should report on the type of participants that are involved with the Programme on a yearly basis.

To this purpose, applicants submitting a proposal for an IHI Call, must complete and upload the [Annex: IHI Type of Participants](#), which consists of an excel table so as to enable IHI meet its reporting obligations on the type of participants. Even though this annex will not be part of the evaluation by the independent experts, **applicants will not be able to finalise their submission without uploading this Annex in the Submission Tool.**

The aim of this document is to provide detailed instructions and concrete examples to the applicants on how to fill in the Annex on the IHI Type of Stakeholders.

Instructions are provided step-by-step, as follows:

1. Overview
2. Definitions
3. Example

1 Overview

The below table describes the information to be inserted in the excel table and provides detailed instructions.

INFORMATION	INSTRUCTIONS
Participant number	<ul style="list-style-type: none"> • Insert the participant number the participant has in the IHI proposal
Participant name	<ul style="list-style-type: none"> • Insert the legal name of the participant
Type of affiliation	<p>This section is applicable only for:</p> <ul style="list-style-type: none"> - IHI private members in Stage 1 proposals that are not part of the pre-identified industry consortium (Short Proposals). Please note, in principle, because contributing partners contribute to the topic that is the subject of the two-stage call, they will not join the applicant consortia for the first stage, but will instead join during, or after, the preparation of the full proposal.

	<ul style="list-style-type: none"> - IHI Private members and/or Contributing Partners in Stage 2 and Single-stage proposals (Full Proposals) <ul style="list-style-type: none"> • In single-stage calls or in the 2nd stage of two-stage calls, IHI private members¹, their constituent and affiliated entities, and IHI Contributing Partners² should insert their type of affiliation from the options below. • IHI private members can select only one option. In case a private member is affiliated to more than one association, please indicate in the comments section the other association(s) it belongs to. <ul style="list-style-type: none"> - <u>COCIR</u> - <u>EFPIA</u> (including <u>Vaccines Europe</u>) - <u>EuropaBio</u> - <u>MedTech Europe</u> - <u>Contributing Partner</u>
<p>Main Stakeholder Type</p>	<ul style="list-style-type: none"> • These are main types of stakeholders that can join consortia under IHI Programme: <ul style="list-style-type: none"> - Research/higher or secondary education organisations (private or public) - Small & medium enterprise (SME) - Mid-cap (For-profit legal entity) - Large company (For-profit legal entity) - Non-governmental organisations (NGOs) - Healthcare professional organisation/Healthcare provider - Patient / citizen organisation - Regulator or Regulatory body - Notified Body - Health technology assessment body (HTA) - Health care payer - Charity and Foundation - Public authority - Other <p><i>The definition for each type of stakeholder can be found in section 2.</i></p>
<p>Stakeholder Type (Level 2)</p>	<p>This section is applicable to:</p> <ul style="list-style-type: none"> • Research / higher or secondary education organisations (private or public) which have to select one of the following options: <ol style="list-style-type: none"> a) universities (including university clinical research) b) research and technology organisations (RTOs) c) other • Small & medium enterprises (SMEs), which have to select one of the following options: <ol style="list-style-type: none"> a) pharmaceutical (incl. vaccine) b) biopharmaceutical

¹ A private member means any legal entity established under public or private law that is a member of a joint undertaking other than the Union, participating states or international organisations; 'constituent entities' means the entities that constitute a private member of a joint undertaking, where the private member is an association according to that member's statutes

² The 'contributing partner' is a health stakeholder who may want to invest in IHI without becoming a full member. Contributing partners invest their own resources (which can be researchers' time, laboratories, data) or cash in a specific IHI project or projects. Their contributions work in a similar way to contributions by private members with the exception of IKAA that the contributing partners do not contribute.

	<ul style="list-style-type: none"> c) medical (and digital health) technologies (continue to Stakeholder Type (Level 3)) d) biotechnology (non-pharma) e) other <ul style="list-style-type: none"> • Mid-cap (For-profit legal entities), which must select one of the following options: <ul style="list-style-type: none"> a) pharmaceutical (incl. vaccine) b) biopharmaceutical c) medical (and digital health) technologies (continue to Stakeholder Type (Level 3)) d) biotechnology (non-pharma) e) other • Large companies (For-profit legal entities) which must select one of the following options: <ul style="list-style-type: none"> a) pharmaceutical (incl. vaccine) b) biopharmaceutical c) medical (and digital health) technologies (continue to Stakeholder Type (Level 3)) d) biotechnology (non-pharma) e) other
<p>Stakeholder Type (Level 3)</p>	<p>This section is applicable to:</p> <ul style="list-style-type: none"> • Small & medium enterprises (SMEs) • Mid-cap (For-profit legal entities) • Large companies <p>Which have selected option c) medical (and digital health) technologies) under Stakeholder Type (Level 2). Please select one of the followin options:</p> <ul style="list-style-type: none"> c.1) medical imaging c.2) radiation therapy (RT) c.3) digital health (including AI) c.4) electromedical equipment c.5) medical devices c.6) in vitro diagnostics (IVD) c.7) other
<p>Comments</p>	<ul style="list-style-type: none"> • Insert here any clarifications if considered necessary. <p>If the option “Other” has been selected under “Main Stakeholder Type” or “Stakeholder Type (Level 2/Level 3), this section should be used to further describe the participant.</p>

2 Definitions

The below table provides definitions of the type of stakeholders that could join consortia under IHI Programme.

TYPES OF IHI STAKEHOLDERS	DEFINITIONS																				
<p>1) Research / higher or secondary education organisations (private or public)</p>	<p>Organisation type:</p> <ul style="list-style-type: none"> • 1.a) Universities (including university and clinical research) • 1.b) Research and Technology organisations (RTOs) • 1.c) Other <p>Definitions:</p> <p>Universities: A university (from Latin universitas 'a whole') is an institution of higher (or tertiary) education and research which awards academic degrees in several academic disciplines. Universities typically offer both undergraduate and postgraduate programs in different schools or faculties of learning.</p> <p>RTOs: RTOs tend to be public or private non-profit organisations that provide a range of research, development and technology services, principally to business and governments.</p>																				
<p>2) Small & medium enterprise (SME)</p>	<p>Small and medium-sized enterprises (SMEs) including start-ups are defined in the EU recommendation 2003/361. The main factors determining whether an enterprise is an SME are:</p> <ol style="list-style-type: none"> 1. staff headcount 2. either turnover or balance sheet total <table border="1" data-bbox="603 1256 1305 1451"> <thead> <tr> <th>Company category</th> <th>Staff headcount</th> <th>Turnover</th> <th>or</th> <th>Balance sheet total</th> </tr> </thead> <tbody> <tr> <td>Medium-sized</td> <td>< 250</td> <td>≤ € 50 M</td> <td></td> <td>≤ € 43 M</td> </tr> <tr> <td>Small</td> <td>< 50</td> <td>≤ € 10 M</td> <td></td> <td>≤ € 10 M</td> </tr> <tr> <td>Micro</td> <td>< 10</td> <td>≤ € 2 M</td> <td></td> <td>≤ € 2 M</td> </tr> </tbody> </table>	Company category	Staff headcount	Turnover	or	Balance sheet total	Medium-sized	< 250	≤ € 50 M		≤ € 43 M	Small	< 50	≤ € 10 M		≤ € 10 M	Micro	< 10	≤ € 2 M		≤ € 2 M
Company category	Staff headcount	Turnover	or	Balance sheet total																	
Medium-sized	< 250	≤ € 50 M		≤ € 43 M																	
Small	< 50	≤ € 10 M		≤ € 10 M																	
Micro	< 10	≤ € 2 M		≤ € 2 M																	
<p>3) Mid-caps companies</p>	<p>Company (for profit legal entity) with an annual turnover of less than EUR 500 million and not under the direct or indirect control of a legal entity of a company of with an annual turnover of EUR 500 million.</p>																				
<p>4) Large company (for-profit legal entity)</p>	<p>Company (for profit legal entity) with an annual turnover of EUR 500 million or more</p>																				
<p>If 2) SME, 3) Mid-Cap or 4) Large company is selected</p> <p>a) Pharmaceutical (incl. vaccine)</p>	<p>Specify which Healthcare industry sector it belongs to (Level 2):</p> <p>The pharmaceutical industry discovers, develops, produces, and markets drugs or pharmaceutical drugs for use as medications to be administered (or self-administered) to patients, with the aim to cure them, vaccinate them, or alleviate the symptoms.</p>																				

<p>b) Biopharmaceutical</p>	<p>The biopharmaceutical industry discovers, develops, produces, and markets biologic(al) medical drugs, or biologic. A biologic is any pharmaceutical drug product manufactured in, extracted from, or semi synthesized from biological sources. Different from totally synthesized pharmaceuticals, they include vaccines, whole blood, blood components, allergenics, somatic cells, gene therapies, tissues, recombinant therapeutic protein, and living medicines used in cell therapy. Biologics can be composed of sugars, proteins, nucleic acids, or complex combinations of these substances, or may be living cells or tissues. They (or their precursors or components) are isolated from living sources—human, animal, plant, fungal, or microbial. They can be used in both human and animal medicine.</p>
<p>c) Medical (and digital health) technology</p>	<p>Medical (and digital health) technologies are products, services or solutions used in a healthcare setting. These can be instruments, equipment, appliances, software, implants, reagents, materials, or other article intended by the manufacturer to be used along the continuum of care. Examples include pregnancy tests, ultrasound equipment, plasters, glasses, stents, MRI, hospital information systems, heart monitor apps, fertility apps, etc.</p> <p>⇒ Drop-down under “Medical Technology” (Level 3):</p> <p>Subset areas:</p> <ul style="list-style-type: none"> • <u>Medical imaging</u> is the discipline in charge of generating internal images of the body. It contributes to better, more accurate diagnoses from the outset and, through ongoing monitoring and measuring, allowing for improved care decisions and more effective treatments and outcomes. <p>X-ray, Computer Tomography (CT), and Nuclear Medicine [Positron emission tomography (PET) and Single-photon emission computerized tomography (SPECT)] all use ionizing radiation, directing high energy particles (photons), to create anatomical, physiological, or functional, images.</p> <p>Magnetic Resonance Imaging (MRI) uses radio waves and a magnetic field to provide detailed images of organs and tissues. Diagnostic ultrasound uses high frequency sound waves to create images of the inside of the body.</p> <ul style="list-style-type: none"> • <u>Radiation therapy (RT)</u> uses photons from X-rays to impact the tumours and destroy its genetic material avoiding its further growth • <u>Digital Health</u> (including artificial intelligence, AI) describes the application of Information and communication technologies (ICT) across the whole range of functions that affect the health sector. It includes tools for health authorities and professionals as well as personalised health systems for patients and citizens.

<p>d) Biotechnology (non-pharma)</p>	<p>The broad range of health digital products and services includes hospital information systems, electronic medical records and other specialty clinical information systems, integrated health information exchange networks, telemedicine and mobile health, secondary-usage non-clinical systems (data analytics, public health, biomedical research)</p> <ul style="list-style-type: none"> • <u>Electromedical equipment</u> includes all the electronic devices that are intended for medical use. They span from machines monitoring patient’s health in intensive care units, like vital signs monitors also used during surgery, to simple devices which monitor single variables like blood pressure devices or glucometers that can be used by the patient himself. • <u>Medical devices (MD)</u>: ‘medical device’ means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: <ul style="list-style-type: none"> ○ diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease, ○ diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability, ○ investigation, replacement or modification of the anatomy or of a physiological or pathological process or state, ○ providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means. • <u>In vitro diagnostics (IVD)</u>: ‘in vitro diagnostic medical device’ means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following: <ul style="list-style-type: none"> (a) concerning a physiological or pathological process or state; (b) concerning congenital physical or mental impairments; (c) concerning the predisposition to a medical condition or a disease; (d) to determine the safety and compatibility with potential recipients; (e) to predict treatment response or reactions; (f) to define or monitoring therapeutic measures. Specimen receptacles shall also be deemed to be in vitro diagnostic medical devices; <p>Biotechnology (non-pharma) sector includes companies that apply science and technology to living organisms to alter living or non-living materials for the production of knowledge, non-pharmaceutical goods and services. Examples are modification of plant genomes for disease resistance or nutrient enhancement, use of genetically modified microorganisms to produce innovative food and feed ingredients plus other</p>
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	product components such as fragrances, cultivated meat, production of bio-oils with photosynthetic micro-algae, biofuel produced through contemporary processes from biomass, etc.
5) Non-governmental organisations (NGOs)	Non-profit, voluntary citizens' groups, principally independent from government, which are organised on a local, national or international level to address issues in support of the public good.
6) Healthcare professional organisation / Healthcare provider	Health care providers encompass organisations that deliver health care goods and services. Typical health care providers are hospitals, long-term care facilities, providers of ambulatory health care, laboratories, nursing care facilities, pharmacies etc.
7) Patient / citizen organisation	<p>Patients' organisations are defined as not-for-profit organisations which are patient focused, and where patients and/or carers (the latter when patients are unable to represent themselves) represent a majority of members in governing bodies.</p> <p>These could be:</p> <ul style="list-style-type: none"> • General umbrella organisations (e.g. representing either European organisations and/or national umbrella organisations), or • European disease specific organisations (i.e. representing national organisations or individual patients on acute and/or chronic diseases).
8) Regulator or Regulatory body	<p>Regulators refers in this document to the different bodies involved in the processes regulating medical products (e.g., scientific assessment, production of scientific guidelines, scientific advice to manufacturers, granting/refusal/suspension of marketing authorisations, post-market surveillance, withdrawing/recalling of devices put on the market, authorisation and oversight of clinical trials). It includes the European Commission, National Competent Authorities (NCA), the Medical Device Coordination Group (MDCG), and the European Medicines Agency (EMA).</p> <p>Notified Bodies, while designated to perform a regulatory function (verification of medical device/in-vitro diagnostics conformity), cannot be considered as regulators in the strict sense of this definition. However, the potential input and expertise of Notified Bodies may still be relevant for the design and implementation of the activities of the proposed initiative.</p>
9) Notified Body	A notified body is an organisation designated - in accordance with (EU) 2017/745 or (EU) 2017/746 - by an EU country to assess the conformity of certain products before being placed on the market. These bodies carry out tasks related to conformity assessment procedures set out in the applicable legislation, when a third party is required. The European Commission publishes a list of such notified bodies.
10) Health technology assessment bodies (HTA)	Health technology assessment (HTA) is an evidence-based multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective health policies that are patient focused and seek to achieve

	<p>best value. HTA focuses specifically on the added value of a new health technology in comparison to the existing standard of care in the health care system. HTA is not only used to inform local/national pricing and reimbursement decisions but also to support the development of evidence-based clinical guidelines and public health recommendations .</p>
11) Health care payers	<p>Payers denote tax-funded national/regional payers and statutory/mandatory health insurance funds (social health insurance, SHI), National Health Services (NHS) and SHI ensuring publicly financed health care (the “benefits package”). In some Member States, additional products and services can be covered by voluntary complementary/supplementary private health insurance</p>
12) Charities and Foundations	<p>Associations typically promote the trade or professional interests of their members, whereas foundations spend their funds on projects or activities that benefit the public.</p> <p>The main characteristics of foundations are:</p> <ul style="list-style-type: none"> • they are run by appointed trustees • their capital is supplied through donations and gifts • they may finance and undertake research • they may support international, national, and local projects • they may provide grants to meet the needs of individuals • they may fund voluntary work, healthcare, and elderly care.
13) Public authority	<p>Public authority means: (a) any government or other public administration, including public advisory bodies, at national, regional or local level; (b) any natural or legal person performing public administrative functions under national law, including specific duties, activities or services in relation to the environment; and (c) any natural or legal person having public responsibilities or functions, or providing public services relating to the environment under the control of a body or person falling within (a) or (b).</p>

3 Example

The purpose of this section is to illustrate, with a concrete example, how the type of participant information can be inserted in the excel table annexed to a proposal. Please note that the drop-down list for Stage 1 proposals (Short Proposals) does not include the option of selecting Contributing Partners. This option is only available for Full Proposals in the 2nd stage of a two-stage Call and in Single-stage Calls.

IHI JU Annex - Type of participants						
PARTICIPANT Number (please follow the proposal order)	PARTICIPANT NAME (please follow the proposal order)	TYPE OF AFFILIATION: ONLY FOR: Member or Contributing Partner if not, please indicate NA (drop-down list)	Main Stakeholder Type (drop-down list)	Stakeholder Type (Level 2) (drop-down list)	Stakeholder Type (Level 3) (drop-down list)	Comments (free text)
1	Univeristy of White Atrium	N/A	Research / higher or secondary education organisations (private or public)	a) universities (including university clinical research)	N/A	
2	IHI Imaging Ltd	COCIR	Small & medium enterprise (SME)	c) medical (and digital health) technologies	c.1) medical imaging	
3	IHI Pharma AG	EFPIA including VaccinesEurope	Large company (For-profit legal entity)	a) pharmaceutical (incl. vaccine)	N/A	
4	IHI Enzymes GmbH	EuropaBio	Mid-cap (For-profit legal entity)	d) biotechnology (non-pharma)	N/A	
5	White Atrium Technologies	MedTech Europe	Mid-cap (For-profit legal entity)	c) medical (and digital health) technologies	c.3) digital health (including AI)	
6	IHI research foundation	Contributing Partner	Charity and Foundation	N/A	N/A	
7	IHI Health Group	N/A	Health care payer	N/A		
8	White Atrium hospital	N/A	Healthcare professional organisation / Healthcare provider	N/A		
9	Innovative Drugs Agency	N/A	Regulator or Regulatory body	N/A	N/A	
10	European IHI patients organisation	N/A	Patient / citizen organisation	N/A	N/A	