Grid of criteria for assessing the impact of innovative technologies

OBJECTIVE

This document has been developed in the framework of Task 8.6 of Work package 8 of the Joint Action "Supporting the increased capacity and competence building of the EU medicines regulatory network" (IncreaseNET). Funded by the European Commission as part of EU4Health programme 2021-2027. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or HaDEA. Neither the European Union nor the granting authority can be held responsible for them.

The development of a "grid of criteria" has been included in the IncreaseNET Grant Agreement as a tool intended to help with the assessment of the impact of innovative technologies on the organization of an NCA. It is a sort of "Impact Assessment Chart" that covers a broad range of assessment criteria to be applied to all sectors of activity of the organization. The aim of this tool is to create a systematic questioning methodology to assess the potential impact of an innovative technology on the organization and to identify actions that would help keeping and strengthening the performance of NCA's regulatory activities. This broad systematic approach would allow the NCA to cover any aspect that could have possibly been impacted and to address related topics that may have not been addressed before.

This document should enable users to better support the assessment of an innovative technology, but also to proactively challenge the NCA's organization in order to anticipate the impact of changes in the regulatory environment and to minimize the potential impact of new technologies on regulators' jobs.

What is considered an "innovative technology" in this grid criteria is a technology for which the NCA's support or assessment standards do not apply to the technology in question (novel technological approach, novel methodological approach, support for the classification of novel medical devices and clinical investigations, absence of regulations and guidelines, limited tools available, need to increase expertise, etc.). This grid criteria covers all phases of development and is adapted to human medicines and medical devices.

(Sustainability action for this tool: it could be proposed to NCAs to set up an Innovation Management Review Team chaired by people charged with innovation watch and composed by representatives of all sectors of the organisation that could be activated when necessary to perform an impact assessment of an innovative technology).

METHODOLOGY to build this "impact assessment Chart":

In order to define the elements of the grid criteria, the team of task 8.6 has designed a survey with questions such as "what have been the biggest challenge in recent years related to the arrival of an innovative technology?", "which procedure(s) has/have been most impacted and how?", "what aspect(s) of the regulatory function have been impacted and how?" and "what has been done to overcome the difficulties encountered?". This survey was shared with all NCA departments in order to identify relevant stakeholders to perform a systematic screening of the different regulatory functions. Interviews were then scheduled and the survey was used as a basis for discussion to identify relevant examples of innovative technologies that had an impact and identify difficulties and solutions implemented to handle it.

STRUCTURE OF THIS DOCUMENT

The document is divided in 4 tabs:
- "readme" to provide context,
- "use example of the grid of criteria" to illustrate how to use this document,
- "grid of criteria" to be completed by respondents, and
- "actions plan template" to build an actions plan on the objectives depending on priorities.

The grid criteria tab is divided in different sections:

1. Identification form: Identify the innovative technology, which procedures are impacted and how.
2. Domain of competence: Identify which domains will be impacted by the innovative technology and how.
    2a. Identification of health product involved: medicinal products, MD/IVD product or combined products
    2b. Identification of domains impacted for human medicines
    2c. Identification of domains impacted for MD/IVD
3. Expertise and competencies necessary
    3a. Evaluation of competencies and training needs
    3b. Evaluation of human resources needs
    3c. Evaluation of tools needs
    3d. Evaluation of regulations needs
4. Prospective NCA organization: Challenge the NCA standard organization and identify if prospective evolutions are needed to support the innovative technology.

ASSESSMENT METHODOLOGY

The user must provide exhaustive answers by going through each sections in the tab “GRID OF CRITERIA”. The purpose of this grid is not to be completed in its entirety, but to ensure that no key point in the management of innovative technology is overlooked. Remember that each section can be opened and closed for a clearer view (using + and - on the left of line numbers).

Each row corresponds to one criterion, the respondent may add as many criteria as wanted by inserting rows. All boxes in column C are free text boxes. The respondent could add any input about the impact of the relevant criteria (e.g. sentences, numbers, crosses, etc.). The column D could be used to define a priority level (high, medium, low) of the criteria or action to be implemented.

Then, the respondent has the possibility to sort answers by column and use the document as a report to support the innovative technology and build an action plan. For information, when the respondant clicks on a line marked with an asterix, a comment is displayed with examples or suggestions to help on the thinking.

Refer to the “GRID OF CRITERIA USE EXAMPLE” tab to find an example and the excel functions mentioned above.

Please **DO NOT DELETE** the line of each section to ensure correct operation of all buttons at the top of the grid of criteria table.

IncreaseNET

Supporting the increased capacity and competence building of the EU medicines regulatory network

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Use these buttons to open / close all sections

Use these buttons to sort by "description/outcome "

Use these buttons to sort the column "priority"

All boxes in column C are free text boxes. Respondents could add any input (e.g. sentences, numbers, crosses, etc.).
It is also possible to add criteria by inseting new rows.

Open or close a section by using "+" or "-" button next to the line number

Section 1

Section 2

	(B) Criteria	(C) Description / Outcome	(D) Priority (high, medium, low)
Identification form			
	Name of the innovative technology	XXX	
	Innovative technology description *	This is the description of XXX	
	Identification date		
	Identification of the innovative technology during which procedure *	MAA	
	References available on the innovative technology		
	Does the technology represent a technological breakthrough? Why? Any advantages vs. the authorized one.		high
	Any other input on identification		
Do not use this line	*Do not use this line*		
Identification of health products categories involved in the innovative technology		**Identification of categories impacted**	
Do not use this line	*Do not use this line*		
Medicinal products **- Identification of domains involved in the innovative technology**		**Identification of staff members impacted**	
Do not use this line	*Do not use this line*		
MD/IVD **- Identification of domains involved in the innovative technology**		**Identification of staff members impacted**	
Do not use this line	*Do not use this line*		
Evaluation of competence gap and training needs		**Identification of training needs**	
	Describe the actual knowledge of the technology (inculding previous SA carried out) and identify the gaps	PV on *module x* , Quality control on *moduce y* , materioviligance on *module z* .	high
	Evaluate risks of the innovative technology from medical and technological point of view *		
	Identify actions to manage the identified risks *		
	Identify if procedures with similar technology have already been assessed *		
	Identify the specific competencies needed to increase the knowledge of the technology *		
	Look for available bibliography: scientific articles, congress' proceedings, scientific advices (via IRIS or FDA), facilitate access to scientific committees reports, etc.		
	Evaluate the impact of the innovative technology on the entire chain of jobs involved in the procedure		
	Identify how existing competencies and expertise could be impacted. What aspects?		
	Evaluate if the technology may have an impact on the qualification of the research / medicine / MD or IVD		
	Evaluate if methodologies can be impacted by the innovative technology *		
	Evaluate if inspection or lab control can be impacted by the innovative technology *		
	Evaluate training needs, priorities and duration *	Short internal training on ATMPs	high
	Identify trainings available: internal trainings, external trainings, European trainings (e.g. EU NTC, Academics), workshops, congresses, etc. *	Not know, need to contact *department 1* and *department 2* .	low
	Evaluate the opportunity to participate in working groups: internal, national, European - EU Innovation Network, Horizon scanning, Task force, etc.		
	Any other input on competence and training needs	Idea to connect with Mrs Smith if she already work on this topic	high
Do not use this line	*Do not use this line*		
Evaluation of human resources needs		**Identification of the impact on human resources**	
Do not use this line	*Do not use this line*		
Evaluation of tools needs		**Identification of impact on tools**	
Do not use this line	*Do not use this line*		
Evaluation of regulation needs		**Identification of impact on regulations**	
Do not use this line	*Do not use this line*		
NCA's organization transformation		**Considerations of foward-looking approaches**	
Do not use this line	*Do not use this line*		

(A) Sections	(B) Criteria	(C) Description / Outcomes	(D) Priority (high, medium, low)
Identification form			
	Name of the innovative technology		
	Innovative technology description *		
	Identification date		
	Identification of the innovative technology during which procedure *		
	References available on the innovative technology		
	Does the technology represent a technological breakthrough? Why? Any advantages vs. the authorized one.		
	Any other input on identification		
Do not use this line	*Do not use this line*		
Identification of health products <u>categories</u> involved in the innovative technology		**Identification of categories impacted**	
Medicinal products	Biosimilars/Biologicals		
Medicinal products	Chemical		
Medicinal products	BTS (Blood/Tissue/Cells)		
Medicinal products	ATMP		
Medicinal products	Hospital preparation		
Medicinal products	Any other medicinal products		
Medical device (MD) / IVD	Class I		
Medical device (MD) / IVD	Class IIa		
Medical device (MD) / IVD	Class IIb		
Medical device (MD) / IVD	Class III		
Medical device (MD) / IVD	In vitro diagnostic		
Combined product	Medicinal products and MD/IVD		
Do not use this line	*Do not use this line*		
Medicinal products **- Identification of <u>domains</u> involved in the innovative technology**		**Identification of staff members impacted**	
Quality	Biological quality		
Quality	Chemical quality		
Quality	Active substance		
Quality	Final product		
Quality	Analytics		
Quality	Viral safety		
Non-clinical	Pharmacovigilance		
Non-clinical	Pharmacokinetics/dynamics		
Non-clinical	ERA		
Non-clinical	Toxicity		
Non-clinical	GCP		
Clinical	Efficacity		
Clinical	Safety		
Clinical	Pharmacovigilance		
Clinical	Pharmacokinetics/dynamics		
Clinical	Interactions		
Clinical	Methodology - Statistics		
Clinical	Pregnancy and fertility		
Clinical	Notice legibility		
Other categories	Pharmaceutical preparation		
Other categories	Pharmacopoeias		
Other categories	Advertising		
Vigilance	Hemovigilance		
Vigilance	Clinical trial		
Vigilance	Pharmacovigilance		
Vigilance	Addictovigilance		
Vigilance	Misuse		
Inspection	GMP: Active pharmaceutical ingredient		
Inspection	GMP: Medicinal products		
Inspection	GCP		
Inspection	GVP		
Inspection	GLP		
Inspection	Pharmacies and/or hospitals		
Inspection	PMF		
Lab control	Lab control		
Lab control	Batch release		
Other human medicines domains	Any other input on medicinal products - Domains impacted by the innovative technology		
	All domains which assure the quality, safety and efficacy of the medicinal product should be evaluated		
Do not use this line	*Do not use this line*		
MD/IVD **- Identification of <u>domains</u> involved in the innovative technology**		**Identification of staff members impacted**	
MD/IVD	Vigilance		
MD/IVD	Qualification / classification		
MD/IVD	Clinical investigation / performance studies		
MD/IVD	Non-clinical		

MD/IVD	Technical and regulatory	
MD/IVD	Medical device quality control	
MD/IVD	Safety and utility	
MD/IVD	Advertising	
MD/IVD	Methodology	
MD/IVD	Quality	
Inspection	Materiovigilance	
Inspection	Inspectors - GCP - To be verified	
Inspection	GLP - To be verified	
Lab control	Lab control	
Other MD/IVD domains	Any other input on MD/IVD - Domains impacted by the innovative technology	
	All domains which assure the quality, safety and afficacy of the medical device should be evaluated	
Do not use this line	*Do not use this line*	
Evaluation of competence gap and training needs		**Identification of training needs**
	Describe the actual knowledge of the technology (inculding previous SA carried out) and identify the gaps	
	Evaluate risks of the innovative technology from medical and technological point of view *	
	Identify actions to manage the identified risks *	
	Identify if procedures with similar technology have already been assessed *	
	Identify the specific competencies needed to increase the knowledge of the technology *	
	Look for available bibliography: scientific articles, congress' proceedings, scientific advices (via IRIS or FDA), facilitate access to scientific committees reports, etc.	
	Evaluate the impact of the innovative technology on the entire chain of jobs involved in the procedure	
	Identify how existing competencies and expertise could be impacted. What aspects?	
	Evaluate if the technology may have an impact on the qualification of the research / medicine / MD or IVD	
	Evaluate if methodologies can be impacted by the innovative technology *	
	Evaluate if inspection or lab control can be impacted by the innovative technology *	
	Evaluate training needs, priorities and duration *	
	Identify trainings available: internal trainings, external trainings, European trainings (e.g. EU NTC, Academics), workshops, congresses, etc. *	
	Evaluate the opportunity to participate in working groups: internal, national, European - EU Innovation Network, Horizon scanning,	
	Any other input on competence and training needs	
Do not use this line	*Do not use this line*	
Evaluation of human resources needs		**Identification of the impact on human resources**
	Evaluate the impact of the innovative technology from a human capacity point of view	
	Evaluate whether enough assessors are available to deal with the specific aspects of the technology (e.g. assessors, assessors with similar competencies in other domains, etc.) *	
	Evaluate the possibility of reallocating resources *	
	Evaluate the possibility of recruiting additional staff	
	Evaluate the need to set up a dedicated team to analyze the impact on resources *	
	Evaluate the need to call on external experts to support the procedure *	
	Evaluate the need to call on additional National, European or international external experts with specific expertise *	
	Evaluate if the experts identified could support the procedure without any contraindication? *	
	Evaluate if specific expertise in the EU or international network is avilable (e.g. other NCA, EU groups, international groups, etc.) *	
	Any other input on human resource	
Do not use this line	*Do not use this line*	
Evaluation of tools needs		**Identification of impact on tools**
	Identify tools that could help to deal with the technology *	
	Evaluate the need to challenge methods and results provided by the applicant	
	Data perspective: How is data on the technology being collected, analyzed, shared, protected and processed?	
	Identify tools that could help on data perspective	
	Identify the need for tools to facilitate the support of the innovative technology *	
	Procedure perspective: Evaluate need for changes in procedures to better support the technology	
	Availability of a tool that promotes collegiality and cross-functionality (e.g. use of a flag to identify specific topics in procedures, tracking procedures already carried out on this technology) - or need to set up/acquire such tool. *	
	Internal or external quality procedures available to facilitate the support of the innovative technology without a standard frame of reference – or need to set up such procedures	
	Any other input on tools	
Do not use this line	*Do not use this line*	
Evaluation of regulation needs		**Identification of impact on regulations**
	Evaluate whether existing regulation/guidelines are enough to regulate the technology and identify the gaps	
	Identify inconsistencies between regulations applicable to the innovative technology	
	Evaluate the need to propose revision or new regulation/guidelines	
	Any other input on regulations	
Do not use this line	*Do not use this line*	
NCA's organization transformation ***To go further in impact assessment***		**Considerations of foward-looking approaches**
	Establish continuity in support of the innovative technology *	
	How to foster polyvalent expertise? *	
	How to foster collegiality? *	
	Need to create a dedicated combined interface to facilitate evaluation of innovative technology *	
	Would a new type of advice be needed to evaluate innovative technology? *	
	Is there a need to create a new type of profession in the NCA? *	
	Modification of the mechanics of existing professions *	
	NCA outward opening *	

	Any other input on organization transformation
Do not use this line	*Do not use this line*

Master contact:

Priority 1:													
General objective 1:													
	Specific objectives	Actions	Person in charge	Priority	Deadline	Status	Start date	Delivery date	Resources required (if applicable)	Budget (if applicable)	Expected results	Outcomes	Explanation of discrepancies	Remarks
1														
2														
3	*(Add specific objectives if needed)*													
General objective 2:													
	Specific objectives	Actions	Person in charge	Priority	Deadline	Status	Start date	Delivery date	Resources required (if applicable)	Budget (if applicable)	Expected results	Outcomes	Explanation of discrepancies	Remarks
1														
2														
3	*(Add specific objectives if needed)*													
General objective 3:													
	Specific objectives	Actions	Person in charge	Priority	Deadline	Status	Start date	Delivery date	Resources required (if applicable)	Budget (if applicable)	Expected results	Outcomes	Explanation of discrepancies	Remarks
1														
2														
3	*(Add specific objectives if needed)*													
Priority 2:													
General objective 1:													
	Specific objectives	Actions	Person in charge	Priority	Deadline	Status	Start date	Delivery date	Resources required (if applicable)	Budget (if applicable)	Expected results	Outcomes	Explanation of discrepancies	Remarks
1														
2														
3	*(Add specific objectives if needed)*													

General objective 2:

	Specific objectives	Actions	Person in charge	Priority	Deadline	Status	Start date	Delivery date	Resources required (if applicable)	Budget (if applicable)	Expected results	Outcomes	Explanation of discrepancies	Remarks
1														
2														
3	*(Add specific objectives if needed)*													

General objective 3:

	Specific objectives	Actions	Person in charge	Priority	Deadline	Status	Start date	Delivery date	Resources required (if applicable)	Budget (if applicable)	Expected results	Outcomes	Explanation of discrepancies	Remarks
1														
2														
3	*(Add specific objectives if needed)*													

Priority 3:

General objective 1:

	Specific objectives	Actions	Person in charge	Priority	Deadline	Status	Start date	Delivery date	Resources required (if applicable)	Budget (if applicable)	Expected results	Outcomes	Explanation of discrepancies	Remarks
1														
2														
3	*(Add specific objectives if needed)*													

General objective 2:

	Specific objectives	Actions	Person in charge	Priority	Deadline	Status	Start date	Delivery date	Resources required (if applicable)	Budget (if applicable)	Expected results	Outcomes	Explanation of discrepancies	Remarks
1														
2														
3	*(Add specific objectives if needed)*													

General objective 3:

	Specific objectives	Actions	Person in charge	Priority	Deadline	Status	Start date	Delivery date	Resources required (if applicable)	Budget (if applicable)	Expected results	Outcomes	Explanation of discrepancies	Remarks
1														

2														
3	*(Add specific objectives if needed)*													