# Use of a Digital Positioning and Categorisation Aid for Clinical Investigations on Medical Devices: Questioning the Complexity of the Field and Harmonizing Stakeholders' Understanding

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Abstract: Medical devices must comply with the safety and performance requirements of the European Medical Device Regulation. For clinical investigations, regulatory approval from competent authorities is required. ICTROUVE is a digital tool designed to help identify the clinical investigation's category when applying to the French competent authority, the *Agence Nationale de Sécurité du Médicament et des produits de santé* (ANSM). We aimed to evaluate ICTROUVE and to prepare a larger-scale study.

This pilot study was divided in two sequences. The aim of the first was to recruit experts and to collect study synopses for which the clinical investigation's category issued by the ANSM was known. To achieve this aim, we created and sent a questionnaire to researchers and regulatory managers via the Tech4Health network. During the second sequence, the experts had to read the synopses and assign them a clinical investigation's category, first without and then with the help of ICTROUVE. A satisfaction questionnaire was then completed.

We found a low decision agreement between experts and ANSM (39% without ICTROUVE, 51.7% with). ICTROUVE was perceived as useful, easy and quick to use. Information was gathered to facilitate a larger-scale evaluation, notably on the collection of synopses and the search for experts..

## 1 INTRODUCTION

Medical devices (MDs) offer a wide range of innovative healthcare solutions. They enable pathological conditions to be diagnosed, monitored, treated or alleviated. They influence patient longevity and quality of life while relieving pressure on the healthcare system ('Medical Devices Must Be Carefully Validated', 2018).

Clinical investigation are related to medical devices and fall within the scope of the European Regulation 2017/745 (MDR) (HAS, 2017; Regulation (UE) 2017/745, 2017).

The MDR brings many necessary advances but it also implies a significant increase in the requirements expected from manufacturers and from notified bodies which must adapt to the new regulations. This has a major impact in terms of cost and time that

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could be difficult to absorb for manufacturers, especially small and medium-sized enterprises, which account for 95% of the total (SNITEM, 2020), and those with a portfolio of old, low-risk products (SNITEM, 2022). Shortages are also envisaged in hospitals (Académie nationale de médecine, 2022; Sayin et al., 2022). Conversely, any reduction in time expended can confer a competitive edge upon a manufacturer in relation to its competitors.

In France, to conduct a clinical investigation (CI) on medical devices, authorisation from the Agence nationale de sécurité du médicament et des produits de santé (ANSM) is essential. However, the acceptance rate in the first round is very low. A study of the 284 dossiers submitted for CI between May 26, 2021, and February 28, 2022, found that only 30 (10.5%) had been accepted outright. In addition, 34 (12%) dossiers for which ANSM had requested additional information were not resubmitted by the manufacturers (ANSM, 2022). Identifying the CI category and compiling the application for authorisation appear thus to be a complex task. Any time-saving assistance would clearly be beneficial to patients and manufacturers alike.

There are several reasons why identifying the right CI category is so difficult. First, not every research using an MD fall under the scope of the MDR. Research using an MD but with a main objective not related to the evaluation of its safety, performance and/or effectiveness may fall under the scope of the French Loi Jardè n°2012-300. This law concerns all Research Involving the Human Person (RIPH in French) with a view to furthering biological or medical knowledge. The approach is based on risk in three types of study. RIPH category 1 is a research implying an intervention on the patient which is not justified by their usual treatment. RIPH category 2 concerns interventional research with minor obligations and risk. RIPH category 3 concerns observational research.

Moreover, for research falling under the scope of the MDR, seven CI's categories exist. The number of decision nodes required to identify the correct one is very large, and the definitions of CI categories are very close to each other. In addition, the definitions are difficult to interpret. Finally, if the personnel responsible for identifying CI categories are qualified, they may be insufficient in number to cope with the required workload (SNITEM, 2020). Category 1 and 2 (CI1 and CI2) concerns clinical investigations on a MD when CE conformity is sought. CI3 concerns a CE-marked DM used in its intended purpose with any additional burdensome/invasive procedure. CI4.1 concerns a CE-marked DM used in its intended purpose with no additional burdensome/invasive procedure. CI4.2 concerns a CE-marked MD (any class), used in its intended purpose without the conformity assessment and including additional procedures. CI4.3 concerns a CE-marked MD (of any class) used outside its intended purpose without the purpose of CE marking or conformity assessment. CI4.4 concerns non-CE-marked MD (all classes) without a CE marking objective.

ICTROUVE is a digital tool designed to help identify the CI's category to which an MD must be subjected. It is a questionnaire produced online, based on the requirements of the MDR and the adaptations made at national level by the ANSM (Chevallier et al.). This tool could save a considerable amount of time in CI authorisation applications. It could also facilitate a more relevant orientation of the investigations and offer a way for developers and evaluators to question their project strategy before submission.

ICTROUVE's efficiency in correctly identifying CI categories compared with the standard method (i.e. as the experts usually do, without ICTROUVE) needs to be evaluated. It means testing the concordance between the CI categories identified with ICTROUVE and the CI categories identified by ANSM. This involves collecting a sufficient number of use cases for which ANSM has issued an opinion. It also implies the participation of a sufficient number of representative experts to carry out the various tests.

The aim of this pilot work was to initiate this evaluation. We present the results of a survey testing the methods for collecting the use cases and recruiting the experts. Another objective of the survey was to obtain feedback on the use of ICTROUVE by researchers and regulatory managers, and thus to identify possible improvements to be made to ICTROUVE. We also intended to obtain an initial assessment of ICTROUVE's ability to identify the CI category.

# 2 MATERIAL AND METHODS

## 2.1 Study Design

Survey using a questionnaire and interviews.

## 2.2 Objectives and Outcomes

The main objective was to prepare a large-scale evaluation of ICTROUVE's ability to correctly identify CI categories.

Secondary objectives were to:

1. obtain information on the actual working methods of the experts responsible for identifying CI categories in French university hospitals;
2. describe the need for assistance in identifying CI's categories;
3. evaluate the use case identification and collection method used to evaluate ICTROUVE;
4. appraise the method used to identify and invite potential experts to participate in the ICTROUVE evaluation;
5. assess the expert's capacity to recognise a clinical investigation compared to a 'classical' RIPH study (studies involving human subjects);
6. compare the performance of ICTROUVE with that of the standard method for identifying the correct CI category;
7. evaluate ICTROUVE usability in terms of ease of use, clarity of questions and user satisfaction;
8. obtain suggestions for improving ICTROUVE by questioning the experts taking part in the study;
9. describe potential failures in the use of ICTROUVE in order to implement corrective measures.

For secondary objectives 1, 2, 7 and 8, assessments were carried out using Likert scales completed at the end of the test series. Likert scales consisted of propositions for which the respondent expressed a degree of agreement or disagreement ('strongly disagree', 'somewhat agree', 'neither agree nor disagree', 'somewhat agree', 'strongly agree').

For secondary objective 9, potential ICTROUVE failures were characterised by the inability to complete all the questions and arriving at a usable result.

## 2.3 ICTROUVE

ICTROUVE is a free online application developed under REDCap (Research Electronic Data Capture) by Louise Bastide, Hugo Potier and Thierry Chevallier of Nîmes' University Hospital.

## 2.4 Study Population

Firstly, a questionnaire was sent to researchers and regulatory managers in several French university hospitals (via the Tech4Health network). The purpose of this questionnaire was to assess the usefulness of a tool to help identify CI categories, to recruit experts and to collect use cases for the second phase of the study.

'Phase 2' was carried out on volunteers referred to in this report as 'experts'. The set of use cases was presented to all participants in the same order (random order). Experts had to classify the use cases collected in phase 1 in 'CI' or 'RIPH'. Then, the experts identified the RIPH category (RIPH 1, 2 or 3) or the CI category (CI1, CI2, CI3, CI4.1, CI4.2, CI4.3 or CI4.4) first without ICTROUVE, then with ICTROUVE. Finally, each participant completed a questionnaire on usability, ease of use and satisfaction with ICTROUVE.

The category identified by ANSM remained secret until the end of the evaluation.

## 2.5 Statistical Analyses

A description of all participants was drawn up for the following parameters: profession, number of years' experience, and workplaces.

Categorical variables were presented in the form of numbers and percentages. They were compared using the Chi2 test or Fisher's exact test.

# 3 RESULTS

## 3.1 Identification and Collection of the Use Cases

Seven use cases were collected. Three concerned RIPH studies and 4 CI studies. For each, we had the study category issued by the ANSM. They were obtained from four University Hospital Centres.

## 3.2 Identification and Invitation of the Experts

Twelve people replied to our contact e-mail. Nine agreed to take part as experts: 4 researchers and 5 regulatory managers. All worked at Besançon University Hospital, except for experts 7 (researcher) and 9 (regulatory manager), who worked at Nancy University Hospital.

Seven (78%) had at least 10 years of experience in their positions, while 2 (22%) had between 1 and 5 years of experience. None had used ICTROUVE prior to this study. Table 1 presents these experts.

Table 1: Experts' participating in study phase 2.

| | Regulatory managers n=5 (55%) | Researchers n=4 (45%) | Total n=9 (100%) |
|---|---|---|---|
| Years of experience | | | |
| >10 years | 4 (80%) | 3 (75%) | 7 (78%) |
| 1 to 5 years | 1 (20%) | 1 (25%) | 2 (22%) |
| University Hospital | | | |
| Besançon | 4 (80%) | 3 (75%) | 7 (78%) |
| Nancy | 1 (20%) | 1 (25%) | 2 (22%) |
| When you have to identify a CI's category, do you usually work : | | | |
| - alone? | 0 (0%) | 1 (25%) | 1 (11%) |
| - in a group? | 0 (0%) | 0 (0%) | 0 (0%) |
| - alone and then in a group? | 4 (80%) | 3 (75%) | 7 (78%) |
| - alone, then in a group for difficult cases? | 1 (20%) | 0 (0%) | 1 (11%) |

## 3.3 Results Regarding the Need for Assistance in Identifying CI Categories

The need for help was unanimously reported (table 2).

Table 2: "Do you think a tool to help you identify the clinical investigation category of a medical device would be useful?"

| | Regulatory manager n=8 (67%) | Researchers n=4 (33%) | Total n=12 (100%) |
|---|---|---|---|
| Yes | 8 (100%) | 4 (100%) | 12 (100%) |
| No | 0 (0%) | 0 (0%) | 0 (0%) |
| Total | 8 (100%) | 4 (100%) | 12 (100%) |

## 3.4 Identification of the RIPH and CI's Category

It took between 45 and 75 minutes for the experts to analyse the 7 use cases and answer the ICTROUVE evaluation questionnaire.

The experts' first task was to recognise which synopses corresponded to RIPH studies (falling under the scope of the Jardè law) and which corresponded to clinical investigations (falling under the scope of the MDR). This task was to be carried out without the help of ICTROUVE, leaving the experts to proceed as usual. The 9 experts analysed 7 synopses each (63 tests have been performed in total). Figure 1 presents the number of synopses adequately recognised as RIPH studies or clinical investigations by regulatory managers and researchers.

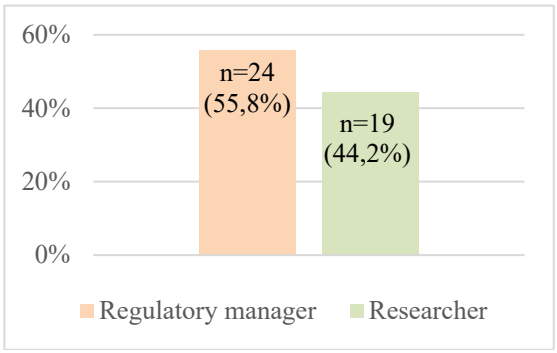


Figure 1: Correct identification of clinical investigations.

Regarding IC's categories, the 9 experts analysed 4 synopses first without and then with the assistance of ICTROUVE (36 tests have been performed in total). Results are presented in Figure 2.

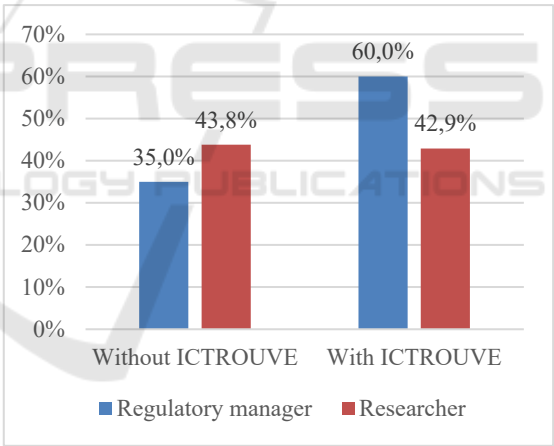


Figure 2: Correct identification of clinical investigations' categories without and with ICTROUVE.

Without ICTROUVE, the correct overall response rate averaged 39% (14 out of 36). For researchers, the correct response rate was 43.8% (7/16). For regulatory managers, it was 35% (7/20) (p=0.734).

With ICTROUVE, the correct overall response rate averaged 42.8% (15/35). For researchers, the correct response rate was 42.9% (6/14). For project managers, the rate was 60% (9/15) (p=0.466).

Out of the 29 CI studies recognised as such by the experts, the application of ICTROUVE yielded divergent results compared to the method without ICTROUVE in 7 (23%) cases. Of these 7 cases, the

use of ICTROUVE resulted in the identification of the correct CI category on 4 (57%) occasions.

## 3.5 Results of the ICTROUVE Usability Survey

The results of the ICTROUVE usability survey are presented in Table 3.

Table 3: Usability survey.

| | Regulatory managers n=4 (50%) | Researchers n=4 (50%) | Total n=8 (100%) |
|---|---|---|---|
| ICTROUVE is easy to use | | | |
| totally agree | 4 (80%) | 2 (50%) | 6 (67%) |
| agree | 0 (0%) | 1 (25%) | 1 (11%) |
| neither agree nor disagree | 1 (20%) | 1 (25%) | 2 (22%) |
| disagree | 0 (0%) | 0 (0%) | 0 (0%) |
| strongly disagree | 0 (0%) | 0 (0%) | 0 (0%) |
| ICTROUVE questions are clear | | | |
| totally agree | 1 (20%) | 1 (25%) | 2 (22%) |
| agree | 3 (60%) | 2 (50%) | 5 (56%) |
| neither agree nor disagree | 1 (20%) | 1 (25%) | 2 (22%) |
| disagree | 0 (0%) | 0 (0%) | 0 (0%) |
| strongly disagree | 0 (0%) | 0 (0%) | 0 (0%) |
| Compared with the standard method, ICTROUVE is more satisfactory | | | |
| totally agree | 0 (0%) | 0 (0%) | 0 (0%) |
| agree | 3 (60%) | 2 (50%) | 5 (56%) |
| neither agree nor disagree | 2 (40%) | 2 (50%) | 4 (44%) |
| disagree | 0 (0%) | 0 (0%) | 0 (0%) |
| strongly disagree | 0 (0%) | 0 (0%) | 0 (0%) |
| Compared with the standard method, ICTROUVE meant that I didn't forget any important criteria when identifying the right CI category. | | | |
| totally agree | 3 (60%) | 0 (0%) | 3 (33%) |
| agree | 1 (20%) | 2 (50%) | 3 (33%) |
| neither agree nor disagree | 1 (20%) | 1 (25%) | 2 (22%) |
| disagree | 0 (0%) | 1 (25%) | 1 (11%) |
| strongly disagree | 0 (0%) | 0 (0%) | 0 (0%) |
| Compared with the standard method, I'm more confident in my ability to identify the right CI category with ICTROUVE. | | | |
| totally agree | 1 (20%) | 0 (0%) | 1 (11%) |
| agree | 1 (20%) | 1 (25%) | 2 (22%) |
| neither agree nor disagree | 3 (60%) | 3 (75%) | 6 (67%) |
| disagree | 0 (0%) | 0 (0%) | 0 (0%) |
| strongly disagree | 0 (0%) | 0 (0%) | 0 (0%) |
| Additional information (definitions, etc.) should be added to facilitate completion. | | | |
| totally agree | 2 (40%) | 1 (25%) | 3 (34%) |
| agree | 3 (60%) | 1 (25%) | 4 (44%) |
| neither agree nor disagree | 0 (0%) | 1 (25%) | 1 (11%) |
| disagree | 0 (0%) | 1 (25%) | 1 (11%) |
| strongly disagree | 0 (0%) | 0 (0%) | 0 (0%) |
| If ICTROUVE's ability to identify the category of a CI was equivalent to that of the usual method, I would prefer to use ICTROUVE | | | |
| totally agree | 1 (20%) | 3 (75%) | 4 (44%) |
| agree | 3 (60%) | 0 (0%) | 3 (33%) |
| neither agree nor disagree | 0 (0%) | 1 (25%) | 1 (11%) |
| disagree | 1 (20%) | 0 (0%) | 1 (11%) |
| strongly disagree | 0 (0%) | 0 (0%) | 0 (0%) |

# 4 DISCUSSION

The European Medical Device Regulation adopted in 2017 strengthens the safety and performance requirements imposed on medical devices (MD). This reinforcement has an impact particularly on clinical investigations (CI), which, in themselves, are already time-consuming and costly.

Our survey suggests that the preparation of CI application dossiers to the ANSM, the French competent authority, is complex. We found little agreement between the CI categories identified by the experts and those finally assigned by ANSM. Concordance was found in only 14 of the 36 cases (39%), even if we could argue that knowledge of the detailed projects could enhance this result.

ICTROUVE could serve as a facilitator for this task. Although some modifications could be considered, the usability survey showed that ICTROUVE did indeed appear to be a good guide, easy and quick to use according to the majority of the participants. The concordance between the CI categories identified with ICTROUVE and those issued by the ANSM was 51.7%. However, its performance needs to be validated by a larger-scale study. This future confirmation will require the participation of experts, such as researchers and regulatory managers, in charge of preparing submission dossiers to the ANSM, and in a sufficient number. It will also require a large number of use cases to be tested. The survey we conducted provided information that could increase the feasibility of these two key aspects of the next stages of this research.

During a webinar on the theme of clinical investigations under Regulation 2017/745, the ANSM presented the results of an analysis examining the 284 CI authorisation applications submitted between May 26, 2021, and February 28, 2022. Within this pool of applications, 46 (16.2%) were in the IC1 category, 47 (16.5%) in the IC2 category, 4 (1.4%) in the IC3 category, 113 (39.8%) in the IC4.1 category, 50 (17.6%) in the IC4.2 category, 11 (3.9%) in the IC4.3 category and 13 (4.6%) in the IC4.4 category. It appeared that 216 (76%) applications were validated, but only 30 (10.5%) in the first round. The very low rate of acceptance in the first round implies additional costs and delays for setting up the CI, or even the abandonment of the project due to the impossibility for manufacturers to respond to ANSM's requests and complete their dossier (in 34 (12%) cases) (ANSM, 2022).

There are several potential reasons for ANSM's refusal at this stage, such as an incomplete application or a request that doesn't align with a CI but rather to a RIPH study. It is important to identify the causes of errors in order to propose appropriate solutions.

A first cause of error might stem from the distinction between CI and RIPH. Indeed, it may be difficult to know whether the research project concerns a clinical investigation of a medical device. In our tests, errors at this stage could concern up to one third of the cases. An additional error could arise from misidentifying the CI category. Participants in our study reported a strong need for help on this particular point. To the question, "Do you think a tool to help identify the clinical investigation category of a medical device would be useful to you?" the 12 experts questioned in phase 1 answered in the affirmative. In addition, several participants expressed a strong lack of confidence in their ability to carry out the CI category identification exercise. This lack of confidence seems to reflect a real difficulty. Our results highlight a significant discrepancy between the categories identified by the experts, with or without the help of ICTROUVE, and the categories validated by the ANSM. Without ICTROUVE, the experts correctly identified the CI category in 39% of cases. With ICTROUVE, this success rate rose to 51.7%.

The number of decision nodes required to identify the correct one is very large, and the definitions of CI categories are very close to each other. In addition, the definitions are difficult to interpret. For example, the sponsor must assess whether the additional procedures provided for in the clinical investigation plan should be considered burdensome and/or invasive. Burdensome additional procedures can include a wide variety of different interventions, including procedures that may cause pain, discomfort, fear or potential risks or side effects, disruption of life and personal activities, or other unpleasant experiences. Burdensomeness is primarily determined from the point of view of the person bearing the burden. Invasive procedures include, but are not limited to, penetration inside the body, including through the mucous membranes of body orifices, or penetration through a body orifice (Medical Device Coordination Group, 2021).

Regarding the use of ICTROUVE, the feedback from our 9 experts was positive, suggesting that it was easily learned, user-friendly and that the questions were clearly formulated. Finally, if ICTROUVE's ability to identify the category of a CI was equivalent to that of the standard method, 7 (77%) participants said they would prefer to use ICTROUVE rather than the standard method.

However, several improvements could be envisaged. After ICTROUVE has been used, a button

to submit a new application would be useful. A majority of participants indicated a need for additional information to facilitate filling in ICTROUVE. The most frequently requested information concerned definitions of MD characteristics (implantable, etc.). One expert would have liked concrete examples to illustrate the questions. Finally, ICTROUVE failed on one occasion in which it proposed no new questions and no results.

The use cases we provided to participants did not mention the class of the MD. This information is essential for identifying the CI category and is complex to determine. This adds a further source of error that can reduce performance with and without ICTROUVE. Participants reported not having to identify the class of the MD in their real working lives. Furthermore, if the purpose of the study was mentioned in the use cases, most participants would have preferred it to be presented unambiguously. In real life, these ambiguities are typically resolved through direct communication with the manufacturer or principal investigator.

This may explain why ICTROUVE, while not judged less satisfactory than the standard method, was not judged more satisfactory either, with 5 (56%) experts "agreeing" and 4 (44%) "neither agreeing nor disagreeing". Similarly, only 3 (33%) participants answered "strongly agree" or "agree" to the question "Compared to the standard method, I'm more confident in my ability to identify the right CI category with ICTROUVE". The remaining 6 (67%) answered "neither agree nor disagree".

There are a number of limitations to this survey. The first relates to the questionnaire used to collect part of the results (Stratton, 2012, 2015). The response rate remains unknown, and the potential for significant differences between respondents and non-respondents has yet to be established. Respondents may not be representative, as a voluntary effect is always possible. It is also possible that the people who responded are precisely those individuals who strongly felt the most important need for assistance in identifying the CIs categories. However, even if, in the worst-case scenario, the study population were not representative of the target population, and even if only some of the experts were to declare a need for help, ICTROUVE's existence would still be justified, provided that this number of people was sufficiently large. The unanimous expression of the need for assistance from all participating experts indicates that such a necessity is widespread.

An additional constraint that could impact the representativeness of the study population is the fact that all the experts belonged to public institutions. The experts involved (in industry, in contract research organisations) may have specific functions and encounter specific difficulties which would be interesting to study. Nevertheless, even if ICTROUVE were to be evaluated and judged as performing well only in the academic arena, this would be sufficient justification for having developed and disseminated it.

It is also possible that the questions were worded in such a way that the opinions and prejudices of the researchers influenced the people who responded to the survey. The questions to be asked in the next steps of our work will have to be carefully worked out and tested to prevent such bias.

Our questionnaire offered the opportunity to participate voluntarily and without obligation but did not give the option of remaining anonymous. These choices may explain the low number of responses obtained, a number which confers reduced statistical power to our study. However, the purpose of this survey was to determine the feasibility of a larger survey, and it therefore did not require significant statistical power (Brooks & Stratford, 2009). This larger study will enable the hypotheses formulated to be tested more rigorously.

In light of the small number of experts recruited for phase 2, we chose to ask them all to identify the CI categories with and without ICTROUVE. It cannot be ruled out that the identification without ICTROUVE had an influence on the identification with ICTROUVE. However, all the experts worked in the same order, first without and then with ICTROUVE, which appeared to us to be the least biased. The use of ICTROUVE is highly standardised, leaving little room for interpretation. Within the framework of the larger study to be conducted, a way to eliminate this bias could be found in the randomisation of experts into "STANDARD method" versus "ICTROUVE method" clusters.

Another limitation is that we were unable to carry out the study under real-life conditions. One of the aims of the survey was to gain a better understanding of how the experts responsible for identifying CI categories work. The information obtained in our survey suggests that, while the identification of CI categories is initially carried out individually, it is often followed by collegial work, which we did not replicate. The next steps will need to consider the possibility of allowing experts to work in groups.

Some of the experts' comments also indicated that they often turn to the manufacturers or principal investigators for further clarification. This mainly concerns technical information on the MD, and information on the purpose and methodology of the study. In the context of the next steps we intend to

follow in our study, this information will have to be taken into account and a solution found to make it available to the experts.

Our search for use cases indicates that they are not yet widely available and are very difficult to collect. As the EUDAMED database is not yet operational on all aspects, synopses have been obtained via university hospitals directly. This data collection method frequently necessitates acquiring authorisation from the principal investigator to utilise information pertaining to their studies. Furthermore, the individuals interviewed during phase 1 indicated a scarcity of use cases available for sharing. An approach involving the ANSM directly would make it possible to obtain a larger number of cases through a single contact, as well as involving the authority for its opinion and input on the ICTROUVE solution.

Collecting a sufficient number of use cases is an essential point. An insufficient number would reduce statistical power, limit the choice of the most appropriate methodology, and make it impossible to work on all existing CI categories. According to ANSM, certain categories are poorly represented (e.g. IC3 and IC4.3). However, it is possible that some CI categories are more difficult to identify.

Finally, we considered that the CI categories identified by ANSM were correct. It is indeed important that ICTROUVE arrives at the same CI categories as the ANSM, since it is the latter that does or does not authorise CIs. However, there could be discrepancies between the ANSM and the new MD regulations. Verifying this hypothesis could be one of the objectives of the next steps.

# 5 CONCLUSIONS

Our work identified a real difficulty for experts and researchers to identify the CI category in France. Inherent difficulties arising from the text issued from the ANSM could constitute an explanation. Another one is that the task is highly complex and requires a great deal of interpretation. It is not unlikely that such a subjective process will be observed in any EU country. A validated computer aid like ICTROUVE could remove the need for interpretation and improve the concordance between competent authorities, researchers and regulatory managers.

Our study points out that a larger-scale study would be useful and feasible. ICTROUVE appears to be well designed, and the few suggestions for improvement put forward by expert users seem straightforward to implement. Finally, the survey gathered information that could prove relevant to the prospective implementation of a larger-scale study, particularly with regard to the process of collecting use cases and finding experts.

It might be worth extending this work to the European level in order to identify possible needs for assistance and to develop a continental tool that would not only simplify national research but also facilitate and harmonise international research.

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