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DECISION-MAKING IN R&D PROJECTS, A FRAMEWORK BASED ON FUZZY LOGIC¹

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Abstract:

In R&D projects, managers face a high degree of uncertainty due to their lack of experience with innovative products. However, managers, usually within a group, have to decide under uncertainty, to make the projects advance. In this context, some delays result from indecision or invalidation of the made decisions. To analyze the causes of these delays, a framework that formalizes the collective decision-making process under uncertainty is proposed. This framework illustrates how the uncertain information is perceived and treated differently by various decision-makers and allows to predict the risk of invalidation of a decision by measuring the dissatisfaction of the agents with the decision. A fuzzy logic approach is used to represent and aggregate human perceptions and reasoning modes. A case study in the pharmaceutical industry is presented to explain the behaviors of different groups of decision-makers, according to their compositions.

Keywords:

collective decision-making process, uncertainty, human factors, fuzzy logic.

1 INTRODUCTION

A R&D project, defined as a process of knowledge acquisition about a new product, involves deciding under uncertainty that comes from innovation in product development process and market dynamics. Many decisions about the new product profile have to be made, throughout the different phases of the project. These decisions are based on the project status information and results of each phase. This information is generally poor compared to what would be necessary to make an informed decision, because the new product is not precisely known. It is only at the end of the project that the accurate information is available. However, project managers have to decide to make the project progress, even if the information is uncertain. These decisions are usually made by a steering committee. The problem is that many delays are observed in collective decisions, in industrial contexts. Either, the decision is postponed, before reaching a compromise between decision-makers, or decisions are regularly invalidated, if the compromise does not satisfy the majority. In order to make more effective and rapid decisions, identifying the causes of these delays is important. In this paper, a framework is proposed that formalizes this process and elucidates how uncertain information is perceived and processed differently by various decision-makers and how the composition of the steering committee affects the collective decision. Human evaluation and reasoning are modeled, respectively by fuzzy sets and fuzzy inference rules. To illustrate the framework, it is applied to a Go / No Go decision milestone of a drug development project.

The structure of this paper is as follows. In section 2, collective decision under uncertainty is presented, taking into consideration human factors. Section 3 details the structure and mechanism of the proposed framework. In section 4, an application case in pharmaceutical industry is presented and the results are discussed. Finally, in section 5, the conclusions and the perspectives are summarized.

2 COLLECTIVE DECISION-MAKING PROCESS UNDER UNCERTAINTY

In order to better understand decision-making process, understanding the notion of uncertainty is first needed [1]. In this section, first objective and subjective approaches to define uncertainty are reviewed. Based on both these approaches, uncertainty is defined. Then the collective decision-making process is studied.

2.1 Defining uncertainty

In academic literature, uncertainty is defined either by emphasizing an object's state which is unknown and unsure in objective approaches [2, 3, 4], or by emphasizing mental states of the subject who is unsure in subjective approaches [5, 6, 7]. However, uncertainty is a relationship between a subject and an object in a specific context. Hence, the following definition is proposed: uncertainty is a subject's conscious lack of knowledge about an object, which is not yet clearly defined (or known), in a context requiring a decision [8].

Based on this definition, a typology is proposed for the factors that cause uncertainty, or influence perception and processing of uncertainty. Figure 1 shows this typology that helps identify and classify these factors in three classes: subject (project manager), object (project), and context (environment). The subject class refers to human factors and is divided into two sub-classes: individual factors such as subject's psychological traits and professional experiences, and collective factors such as contradictory opinions and debates. The object class refers to the states of the object that are not stable and could be changed and affect the subject's objectives which depend on the object's states. The context class refers to the circumstances of the decision and is divided into two sub-classes: the internal environmental factors such as organizational and hierarchical elements of the company, and the external environmental factors such as market dynamics, competitors' activities, stakeholders' expectations, and regulatory changes. Therefore, uncertainty should not

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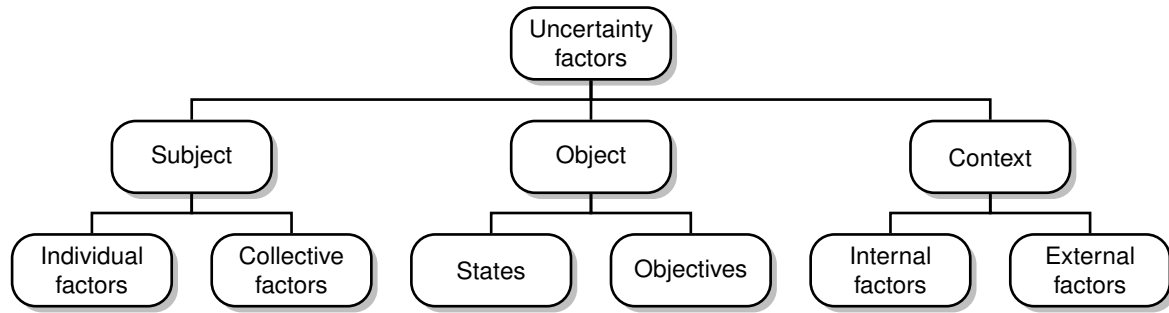


Figure 1: typology of uncertainty factors

be studied emphasizing only the object, separately from the subject and the context. However, as far as we know, human and contextual factors are less studied compared to objective factors. The proposed typology allows taking human and contextual factors into account, to perceive and process uncertainty.

2.2 Decision as a process

Decision-making is an important part of any organization [9]. Simon criticizes the images that falsify the decision by focusing on the final moment. He suggested that “a decision is not an act, but a process” [10]. A fighter pilot, John Boyd, studied military decisions in the Korean War (1950-1953) and proposed a loop of four box method to model these decisions: Observe-Orient-Decide-Act. The step Observe involves collecting and communicating the information. The step Orient consists in understanding and appreciating the situation and its possibilities. The step Decide concerns the determination an action, and finally, the step Act is playing out the decision [11, 12]. Another decision-making iterative process has been proposed by Simon: Intelligence-Design-Choice-Implementation. The Intelligence stage as the first stage includes observing reality, identifying the problem, and collecting information. The Design stage is composed of two sub-stages: identification of the criteria and construction of the alternatives. The first sub-stage focuses on identification and specification of the important criteria for decision, and measurement the relationships between them. The second sub-stage focuses on identification, analysis, invention, development, and conceptualization of the alternatives. The Choice stage is what most people think of as making a decision [13]. This stage focuses on the evaluation of the alternatives and development of the actions that satisfy the criteria of decision [10]. The last stage is added by later researchers. The Implementation stage consists in weighing the consequences of the actions, gaining confidence on decision, and planning the actions. A vigilant decision-making process is proposed by Janis and Mann and takes into account any new information or expert judgment to support the choice process, even if the new information invalidates the initial perception [14].

The mentioned frameworks propose to consider decision as a process instead of an act. It helps studying different mental activities that contribute to decision-making. It also highlights the role of different actors in each stage of the decision. Additionally, decision and information are connected in these processes. For example, Simon’s framework “makes it possible to connect decision and information, even though it is not rich enough in terms of understanding choice and analyzing the role of future events” [11]. Furthermore, data, information, and knowledge transformation by cognitive processes throughout decision-making process is not outlined. Cognitive processes are defined as the processes that involve

information processing in some sense [15]. Data are the uninterpreted signals detected by senses, information is data equipped with interpretation and meaning, and knowledge is the whole data and information that are used to carry out tasks and create new information by reasoning [16]. These distinctions are useful to understand the mental mechanisms of a decision-maker, and to study the factors that contribute to this transformation process and consequently to decision-making process. In collective decisions the transformation process can be different for various decision-makers.

2.3 Collective choice as a compromise

In the case of collective decision, the process mainly consists in the interactions between decision-makers. The process would usually be composed of a period of individual reflections and group interactions [17]. Therefore, individual differences within a group play an important role in the interactions between decision-makers. “All decision is a matter of compromise. The alternative that is finally selected never permits a complete or perfect achievement of objectives, but is merely the best solution that is available under the circumstances” [18]. Hence, individual and collective human factors, context and circumstances of the decision are all important to study the collective decision-making process. Some of these elements are taken into consideration in the proposed framework, presented in the next section.

All the mentioned processes give a structure to decision. However the Choice stage, though it might be the most intellectually difficult part of the decision-making process [13], is not enough developed in the literature. The cognitive processes, that help a decision-maker transform data to information and knowledge, are not outlined. Moreover, collective and individual decisions are related but not structured. Hence, the causes of delays in collective decisions cannot be studied, only leaning on these processes. The proposed framework develops, analyses, and formalizes the Choice stage, taking into account human cognitive processes such as perception, evaluation, and reasoning. It helps identify the causes of the delays in collective decisions, especially when information is uncertain.

3 FRAMEWORK FOR COLLECTIVE CHOICE STAGE

Suppose a group of A decisional agents (decision-makers) have to make a collective decision d , that is shaped by individual decisions d_a , where $1 \leq a \leq A$. The input of the collective decision is a vector of variables $[v_i]$, where $1 \leq i \leq I$, and I is the number of the variables that are judged, by the group in Design stage, to have an impact on decision, satisfying a set of already determined criteria. Each agent receives the same values for the I variables and processes them through three personal cognitive processes: perception, evaluation, and reasoning before leading to the individual

decisions d_a and then to the collective decision d . Figure 2 illustrates the structure of this framework. The rectangles represent the cognitive processes, and the lozenges represent the decisions. The pointing down arrows correspond to the constraints and the pointing up arrows correspond to individual or collective influential factors.

Perception

Perception is triggered by sensory stimuli from the environment, the detected data that could be transformed in information. Here $[v_i]$ represents the input of the perception process, i.e. the data that is processed by all the agents. The memory and the objectives of agent a , respectively represented by the sets M_a and O_a help perceive, filter, and select the variables that have a signification and importance to agent a . Hence, the output of this process is a vector $[p_{ai}]$ that represents the perception of the selected variables by agent a . An agent might not take into consideration all variables, either because they are not meaningful to him or they do not concern his objectives. Thus, the selected variables are not the same for all agents. The vector $[p_{ai}]$ is the input of the next cognitive process.

Evaluation

Evaluation consists in comparing the value of each variable to the objectives that concern this variable. Evaluation is influenced by the objectives O_a and the knowledge of agent a noted K_a . The human evaluation of both qualitative and quantitative variables is expressed by linguistic terms that are often not binary. For example, the value of variable v_i can be a number, an interval, or a modality. In all cases, v_i is qualified by agent a via a set of linguistic terms, such as $E_{ai} = \{bad, average, good\}$. Then for example, the evaluation of p_{ai} (the perceived value of variable i by agent a) can be noted $e_{ai} = bad$. The set of linguistic terms to qualify the same variable might be different for all agents a . The representation of these linguistic terms in a formal language allows applying logic operators to evaluate them. Fuzzy sets [19] are not sharp-edged, contrary to classical sets whose borders are strict and do not allow an object to be located at the border between two sets. For this reason, the linguistic terms that express the evaluations of variables can be modelled by fuzzy sets. The gradual membership functions allow a value to belong to each set, that represents a linguistic term, to a certain degree. For example, the value of the variable of the altitude of a mountain can vary between 500 meters and 8848 meters. The value of this variable could be evaluated by a set of linguistic terms such as *low*, *medium*, *high*, *very high*. The output of the evaluation of 3000 m could be as follows: 0% *low*, 60% *medium*, 30% *high* 0% *very high*. In doing so, the output of the evaluation is a vector $[e_{ai}]$ whose components are the degrees of membership to the sets of linguistic terms, that express the evaluation of p_{ai} by agent a . The vector $[e_{ai}]$ is the input of the reasoning process.

Reasoning

Reasoning consists in measuring how the selected variables by agent a globally satisfy his objectives O_a . To measure his satisfaction of a given situation, agent a applies a set of N inference rules based on his knowledge K_a and his objectives O_a . The inference rules can be implicit for an agent and can be different from the rules of the other agents. The framework allows to explicit and formalize these rules and consequently, highlights theses differences. Human inference rules are not binary and strict. A Fuzzy Inference System (FIS) makes it possible to create non-binary rules,

based on fuzzy sets that represent the qualifying linguistic terms. Therefore, a FIS is applied to model the creation and the aggregation of these rules. The inference rule number n , where $1 \leq n \leq N$, created by agent a , noted $rule_{an}$, is defined as follows: $rule_{an} : \prod_{i=1}^I E_{ai} \rightarrow R_a, \forall a$ and $\forall n$, where R_a is a set of linguistic terms, created and used by agent a to qualify a perceived and evaluated situation $[e_{ai}]$. In doing so, $rule_{an} : (e_{a1}, \dots, e_{ai}, \dots, e_{aI}) \rightarrow r$, where $r \in R_a$, symbolizes the rule number n of agent a . For each input (situation) such as $[e_{ai}]$, several rules could be activated with different degrees. The aggregation of these rules, noted r_a , gives a result for reasoning process. The r_a is not a vector but a qualifying linguistic term that expresses the appreciation of the situation by agent a . It represents his new knowledge about this situation thanks to his reasoning. The r_a is then the input of the individual decision.

Individual decision-making

Individual decision-making involves choosing an option based on a balance of benefit/risk of the options. An agent chooses an option based on his reasoning, the result of the precedent process. Individual decision is influenced by his objectives O_a , responsibilities $Resp_a$, knowledge K_a , previous experiences E_a , and psychological traits Ψ_a . Additionally, the consequences of the decision for an agent C_a play an important role in this process. In a collective process, the individual decision is rather a tendency or a recommendation of each agent. Here, agent a transforms the r_a to one of the options of the decision, assuming the consequences of his proposition. The output is not a vector, but the recommended option by agent a , noted d_a and is one of the components of the input vector for the collective decision-making, noted $[d_a]$.

Collective decision-making

Collective decision-making aims at reaching a compromise between agents. This process is influenced by interactions between different agents. A FIS is used to reproduce the collective decision. A set of inference rules expresses the different interactions. These rules depend on the composition of the group, and the hierarchical position of each agent. The aggregation of these inference rules gives the collective decision. The output is one of the options of the decision. The difference between the collective decision and the individual decision expresses the degree of the dissatisfaction of the agent: $Dis_a = |d - d_a|$. If this indicator is high for several agents, the decision could be invalidated in time. It does not mean that if all agents agree, the decision is "good". It is an indicator that measures the risk of invalidation of a decision, and so the delays in decision.

The proposed framework is simplified compared to the reality, supposing that: 1) the agents agree, in Design stage, about the list of the variables on which the decision is based and on the possible options, as the output of the decision. Thus, the input of all individual decision processes is the same and the output cannot be a new option, 2) for each agent, one's individual decision-making process is composed of four cognitive processes: perception, evaluation, reasoning, and individual decision, 3) the four mentioned processes are all influenced by the memory, knowledge, experiences, psychological traits, and the objectives of the agents. For each process, the main influential factors are kept. For example, the memory is implicated throughout the four processes, however its role is more important in the perception process.

The proposed framework formalizes the Choice stage of collective decision process and helps understand how each

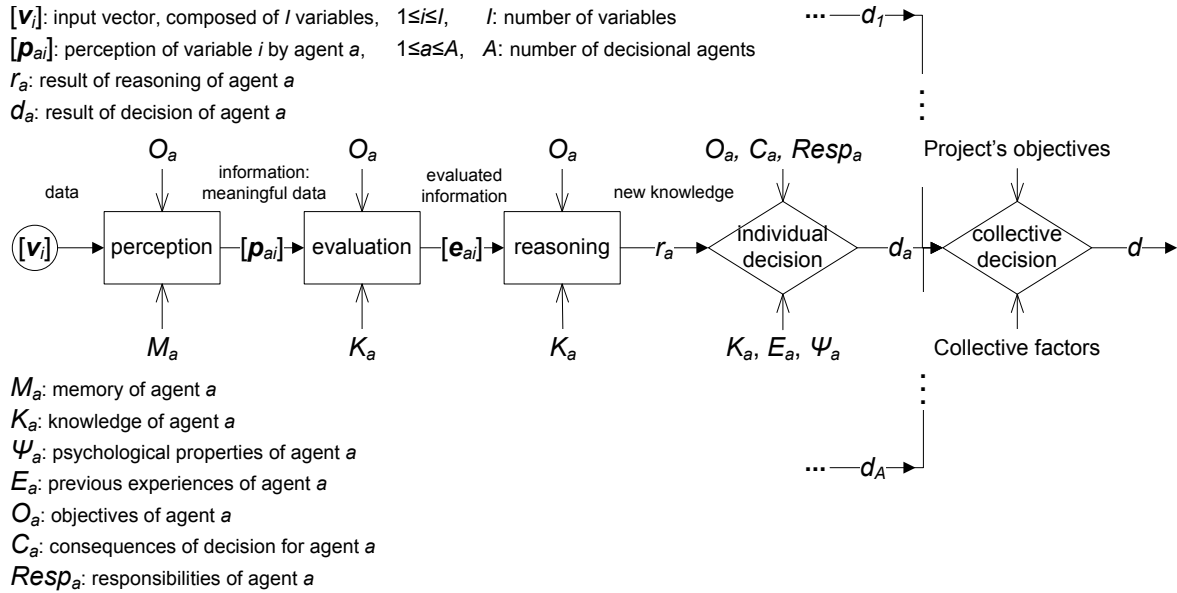


Figure 2: framework for collective Choice stage

agent can take into account different variables and reason differently from the other agents.

4 APPLICATION CASE TO PHARMACEUTICAL R&D PROJECTS

Decision-making in R&D faces much uncertainty in all industries. In pharmaceutical industry, the degree of uncertainty about the behavior of the new compounds in the human body is high. A drug development project is defined as a process that allows a presumably active compound to become a pharmaceutical drug [20]. These projects last an average of 13 years and cost more than \$800 million, with a success rate of only 4% [21]. Many questions must be answered about the safety, efficacy and quality of the compound, throughout a series of tests in different phases of the project. The Go/No Go decision milestones mark the different phases of the project. Throughout these milestones, a steering committee decides whether to continue or stop the project. These decisions are based on the results of the tests and studies that are generally very poor compared to what would be necessary to make an informed decision. Several interviews with the pharmaceutical decision-makers confirm that decisions are made with lengthy delays, especially at the end of the phase II, because the transition to the phase III implies taking risks to human health and involves an important time and financial investment. Hence, the main characteristics of our problem are gathered in these projects: delays or invalidation of collective decisions that are made under uncertainty. In this section, the proposed framework is applied to the Go/No Go collective decision of the phase II.

4.1 Go/No Go decision milestone of the phase II

The various studies and tests of a R&D project aim at determining the benefit/risk ratio of the new compound. For example, the main goal of the tests of the phase II is to establish the efficacy and safety windows of the compound in the target population (patients), by identifying the minimal effective (*Efficacy*) and the maximal tolerated (*Tolerance*) doses on this population [22]. The first assessment of efficacy is made in this phase. However, the minimal tolerated dose was previously documented on healthy volunteers (aim of phase I studies). Another parameter that is evaluated is

the Cost of Good (*COG*) based on the cost of chemical development. To simplify this example, it is supposed that there is not any toxicity or kinetics alert in the results of previous tests that prevents starting the phase II. The other variables, studied in this phase, such as the stability of the compound and its metabolism are incontestably good. Finally, the relation between dose and activity is presumed linear and positive. In doing so, the Go/No Go decision milestone at the end of the phase II is based on three uncertain variables: *Efficacy*, *Tolerance*, and *COG*. Referring to the proposed typology in section 2.1, the three types of uncertainty factors are identified: 1) subjective factors: the uncertain results of the tests are perceived differently according to the personality, psychological properties, previous experiences, and speciality of each decision-maker. 2) Objective factors: in spite of the obtained results, the behavior of the compound is not completely predictable. The results of the tests, carrying out on a limited number of patients, cannot be generalized to the whole target population. 3) Contextual factors: in a competitive industrial context, is the compound more effective, better tolerated, or less expensive than the existing or competitive products? Some of these factors are taken into account in the application of the proposed framework.

4.2 Description of the example

The collective Go/No Go decision milestone at the end of the phase II is modeled by the proposed framework. To simplify the example, the interdependencies between the variables have been ignored and the steering committee is limited to three decisional agents: a_1 : clinician, a_2 : toxicologist, and a_3 : economist. The input vector is:

$$[v_i] = (v_1, v_2, v_3) = (Efficacy, Tolerance, COG). \quad (1)$$

Where *Efficacy* and *Tolerance* can have a value between 0 and 200 mg and *COG* can have a value between 0 and 10000 €/kg. The agents must decide whether to stop the project, if the results are "bad", or to put the project on standby, if the results are not conclusive enough and complementary studies are requested, or to continue, if the results are "good" enough. Thus the output is one of these options: No Go/Standby/Go.

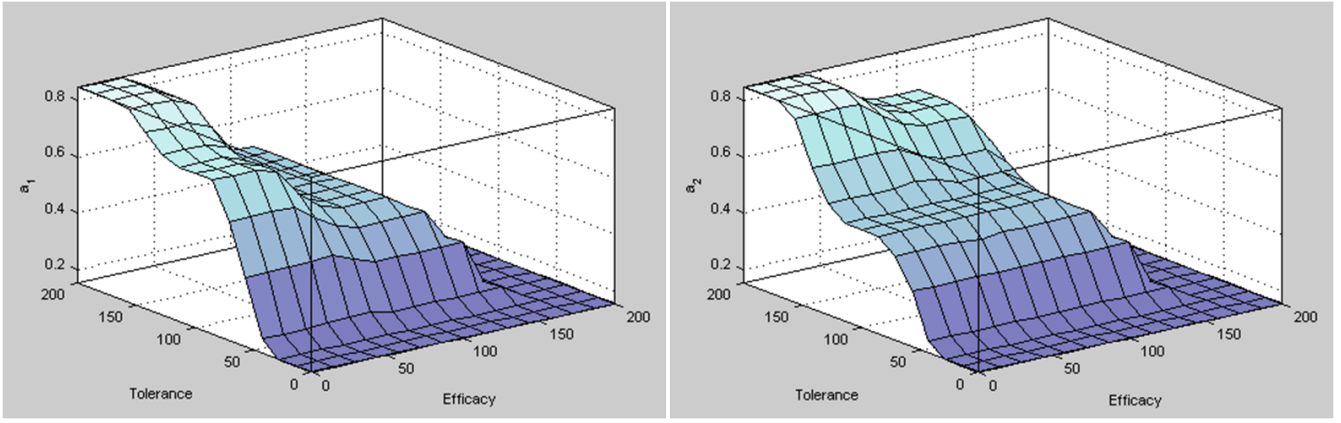


Figure 3: surfaces of the result of the reasoning process illustrate that *Efficacy* is more important than *Tolerance* for a_1 , on the left and *Tolerance* is more important than *Efficacy* for a_2 , on the right.

Perception

The value of each variable is perceived by each agent and is transformed to a meaningful data. Supposing that all variables are meaningful for a_1 and a_2 , but v_1 is not meaningful to a_3 . Thus a_3 does not keep it. The outputs of a_1 , a_2 , and a_3 are as follows:

$$[p_{1i}] = (p_{11}, p_{12}, p_{13}), \quad (2)$$

$$[p_{2i}] = (p_{21}, p_{22}, p_{23}), \quad (3)$$

$$[p_{3i}] = (-, p_{32}, p_{33}). \quad (4)$$

Evaluation

The knowledge of each agent helps him to evaluate the perceived variables, in terms of satisfaction of one's objectives. For example, a_1 knows that if less than 50 mg of the new compound has a significant difference on *Efficacy*, comparing the placebo group, it is unarguably effective, a_2 knows that if more than 200 mg of the new compound is tolerated, then *Tolerance* is unquestionable, and a_3 knows if the *COG* is less than 2500 €/kg, it is obviously good. It should be noted that in the same situation, a_1 and a_2 evaluate all variables, and a_3 evaluates the variables that he kept. These evaluations can be different for the same variables:

$$[e_{1i}] = (e_{11}, e_{12}, e_{13}) = (average, good, good), \quad (5)$$

$$[e_{2i}] = (e_{21}, e_{22}, e_{23}) = (good, average, good), \quad (6)$$

$$[e_{3i}] = (-, e_{32}, e_{33}) = (-, good, average). \quad (7)$$

Reasoning

The reasoning process is based on the inference rules that depend on the importance of the variables to agent a . For example, *Efficacy* and *Tolerance* are more important respectively to a_1 and a_2 . This difference is expressed via two different rules:

$$rule_{11} : (good, average, average) \rightarrow satisfactory, \quad (8)$$

$$rule_{21} : (good, average, average) \rightarrow average. \quad (9)$$

Figure 3 illustrates the impact of this difference of point of view on the reasoning's output.

Individual decision-making

The individual decision does not only result from the reasoning process. The individual factors, explained in section 2.1, have an impact on individual decisions. For example, personal risk aversion and taste for risk can conduct a situation, appreciated as average, respectively to the No Go and Go options.

Collective decision-making

The collective factors, explained in section 2.1, have an impact on the collective decision. Table 1 shows the collective decisions of two groups: the recommendation of a_3 is more important in g_2 comparing to g_1 . The results show that the composition of the group and the position of each agent within the group can change the collective decision for the same situation. The results are discussed in the next section.

4.3 Validation of the framework

A FIS is applied to simulate the individual and collective decisions of the phase II. Table 1 shows these simulations. The first column includes 9 input vectors. The columns 2, 3, and 4 represent the decisions of the specialists. Each decision has a value between 0 and 1 that is translated to an option. The two last columns show two collective decisions of the groups g_1 and g_2 .

Table 1: simulation results

Situations	Decisions				
	Individual	Collective			
Inputs	a_1	a_2	a_3	g_1	g_2
[180, 50, 9500]	0.15	0.15	0.15	No Go	No Go
[90, 130, 4100]	0.50	0.50	0.50	Standby	Standby
[40, 190, 2500]	0.84	0.84	0.71	Go	Go
[35, 130, 5500]	0.72	0.55	0.50	Go	Standby
[100, 190, 4900]	0.50	0.70	0.50	Go	Standby
[130, 80, 1000]	0.55	0.55	0.55	Standby	Standby
[25, 200, 8000]	0.70	0.70	0.15	Go	No Go
[25, 200, 5000]	0.84	0.84	0.50	Go	Go
[25, 200, 1000]	0.84	0.84	0.84	Go	Go

The inputs have been chosen to study the behavior of the model according to: 1) the behavior of each agent and 2) the composition of each group. In the three first inputs, all the variables have the same evaluation in each column. The results show that all agents and two groups agree on the output. In rows 4 and 5, at least one of the *Efficacy* or *Tolerance* is evaluated good, while the other one and the *COG* are evaluated average. In rows 4 and 5, respectively, the clinician and the toxicologist decide to go, while the others decide to postpone the decision. In the two cases the decision of g_1 is to go, while the decision of g_2 is to stop, since a_3 has more influence in g_2 . In row 6, even *COG* is evaluated good, the two other variables are average. Both groups decide to postpone the project, because in all cases *Efficacy* and *Tolerance* are more important than *COG*. In

the three last inputs, *Efficacy* and *Tolerance* are evaluated good and are fixed to study the impact of the variations of *COG* on the decisions. When *COG* is not bad (rows 8, 9), both groups decide to continue. When *COG* is bad (row 7), g_1 decides to continue and g_2 decides to stop, since a_3 has more power in g_2 .

4.4 Application of the framework

Figure 4 illustrates an application case. For one situation the behavior of the two groups are simulated. The result show the dissatisfaction of a_3 with the decision of g_1 is: $Dis_3 = |d - d_3| = 0.56 - 0.15 = 0.41$. Therefore, the decision could be invalidated a posteriori. The framework help study and analyze previous conflicts in decisions and can predict future conflicts, according to the position of each agent and the composition of the group.

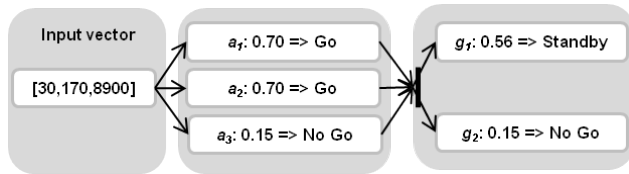


Figure 4: application case

5 CONCLUSIONS AND PERSPECTIVES

Collective decisions under uncertainty are delayed for two reasons, either the decision-makers cannot decide at all (indecision) or they regularly invalidate the decision-making. The causes of these delays should be identified in order to help decision. In this paper, first uncertainty is defined. The factors that contribute to characterize, perceive, and process uncertainty are structured in a typology, taking into account subjective, objective, and contextual factors. Then a framework to formalize the collective Choice stage of the decision-making process is proposed. In the proposed framework the transformation of data, to information, and knowledge is outlined via the individual cognitive processes: perception, evaluation, and reasoning. Fuzzy sets are applied to model human evaluation and reasoning with uncertain values. An application case, in Go/No Go decision milestones in pharmaceutical R&D projects is presented to illustrate the proposed framework. The framework helps explicit inference rules used by the agents to decide in order to analyze their different behaviors in the group and outlines that a collective decision is influenced by: 1) composition of the group, 2) position of each agent in the group. The framework allows to predict the risk of invalidation of a decision by measuring the dissatisfaction of the agents.

In the proposed framework, the input, the sequence of cognitive processes, and the influential factors of each process are supposed to be the same for all agents. The iterative aspect of decision, the interdependencies between the variables, and the interactions between agents are not taken into account. In a new version of the framework these limitations could be improved and more human factors could be taken into account in order to better represent the reality of the decision. Finally, the mechanism of the framework can be applied to the other stages of the decision-making process such as Intelligence and Design.

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