

A Knowledge Engineering-Oriented Process Model for AI-Enabled Decision Support Systems Aligned with the EU AI Act and Relevant ISO/IEC Standards

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Abstract

The development of Artificial Intelligence (AI)-enabled Decision Support Systems (DSS) for complex domains requires structured development processes capable of integrating expert knowledge with data-driven analysis while ensuring transparency, traceability, and explainability throughout the lifecycle. Although existing methodologies address either Knowledge Engineering or Machine Learning, they generally treat these disciplines independently and do not provide a unified process that coordinates their activities within a common development framework. This paper presents a process model for the development of AI-enabled DSS that combines Knowledge Engineering with data-driven analysis, including Machine Learning techniques when applicable, under a single methodological approach. The proposed model is organized into five phases, covering the entire development process from project definition to system implementation, while establishing traceability with selected provisions of the European Union Artificial Intelligence Act and the ISO/IEC 22989, ISO/IEC 23053, and ISO/IEC 5392 standards. Unlike the methodologies discussed in the literature, the proposed model coordinates knowledge elicitation, data-driven analysis, hypothesis validation, reasoning model specification, and regulatory traceability within a single artifact-oriented lifecycle. It provides explicit mechanisms for integrating expert knowledge and domain data and is intended to support the development of explainable, traceable, and trustworthy AI-enabled Decision Support Systems. In its current formulation, the process culminates in the specification and implementation of a fuzzy inference-based DSS, selected to represent expert reasoning under uncertainty and imprecision. The resulting methodology provides multidisciplinary AI teams with practical guidance for engineering this class of systems.

Keywords

Knowledge Engineering, Artificial Intelligence System, Decision Support System, Process Model, Standardization

1. Introduction

The European Union Artificial Intelligence Act [1] defines an Artificial Intelligence System (AI System) as a “*machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments*”. That is, an AI System is developed and executed on hardware and software components and may be designed to operate with a certain degree of autonomy from human intervention. This autonomy entails the capability to function independently, even without direct supervision. AI systems may also exhibit adaptability, understood as the capacity for self-learning that enables them to modify their behavior during operation, potentially producing different outputs in response to the same inputs. Such systems may be deployed as standalone solutions or as components integrated into an already operational product. Another relevant aspect is that AI systems have inference capabilities. This capability refers to the process of deriving outputs from the information received as input through machine learning and/or logic- and knowledge-based approaches, thereby

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encompassing different mechanisms for producing AI-generated results. The International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC), in ISO/IEC 22989 [2], define inference as the reasoning process through which conclusions are obtained from known premises, where a premise may consist of a fact, a rule, a model, a domain feature, or raw data. This ability to generate outputs is associated with the construction phase, during which a system produces results by applying AI techniques that enable inference. Techniques that support inference in the construction of AI Systems include both machine learning strategies, which learn from data how to achieve specific objectives, and logic- and knowledge-based strategies typical of Knowledge Engineering, which infer from encoded knowledge (such as rules or facts) or from a symbolic representation of the task to be solved through formalisms based on rules, ontologies, or knowledge graphs. Therefore, inference capability transcends basic data processing by enabling learning, reasoning, and modeling.

In ISO/IEC 5392 [3], Knowledge Engineering is defined as the *“discipline concerned with acquiring knowledge from domain experts and other knowledge sources and incorporating it into a knowledge base”*, whereas ISO/IEC 23053 [4] presents Machine Learning as *“a branch of AI that employs computational techniques to enable systems to learn from data or experiences”*. However, the effectiveness of Machine Learning approaches depends strongly on data quality, and some models may provide limited interpretability due to their black-box characteristics [5, 6]. In this context, the combination of Knowledge Engineering and Machine Learning makes it possible to complement the respective strengths and weaknesses of both approaches [7], thereby enabling more systematic integration of empirical evidence and explicit domain knowledge. On the other hand, depending on the objectives established for the AI System, different types of outputs can be obtained, enabling the development of: (a) Prediction Systems, which perform regression tasks when predicting quantitative outcomes and classification tasks when predicting qualitative outcomes, thereby supporting the anticipation of future behaviors or scenarios [8]; (b) Recommender Systems, which provide users with personalized suggestions according to their needs. These recommendations support a wide variety of decision-making processes, such as selecting products to purchase, music to listen to, or news articles to read [9]; (c) Content-Oriented Systems, whose output consists of the autonomous generation of different forms of content, ranging from plain text to images, audio, and video [10]; and (d) Decision Support Systems, which integrate data and knowledge to assist organizational decision-makers in addressing complex, uncertain, or ill-structured problems [11].

Decision Support Systems (DSS) continue to attract significant attention in both research and practical applications. Recent bibliometric studies [12, 13] report a sustained increase in publications and citations across a wide range of application domains, including healthcare, logistics, and finance. Despite this growing interest, the development of AI-enabled DSS is generally approached through methodological frameworks that focus either on the explicit representation of domain knowledge using Knowledge Engineering or on data-driven analysis using Machine Learning techniques, without providing mechanisms to integrate these complementary perspectives throughout the lifecycle [14, 15]. At the same time, recent international regulations and standards introduce new requirements regarding transparency, traceability, governance, and accountability. However, there is still no unified process model that explicitly integrates these dimensions into the development of AI-enabled DSS. To address these limitations, this paper proposes a process model for the development of AI-enabled DSS that integrates Knowledge Engineering with data-driven analysis, including Machine Learning techniques when applicable, within a unified methodological framework. The proposed model comprises five interconnected phases that coordinate knowledge elicitation, data-driven analysis, hypothesis validation, and reasoning model specification while maintaining traceability with the European Union Artificial Intelligence Act [1] and the frameworks established by ISO/IEC 22989 [2], ISO/IEC 23053 [4], and ISO/IEC 5392 [3]. In addition, particular emphasis is placed on Knowledge Engineering techniques, including ontologies, knowledge maps, and knowledge elicitation, together with hypothesis validation as a mechanism for integrating expert knowledge and data-driven analysis, thereby facilitating the incorporation of human context and expert reasoning into AI-enabled DSS [16]. In the current formulation of the proposed process, the reasoning component is instantiated through fuzzy inference, since this approach enables the explicit representation of expert knowledge and uncertainty through

linguistic rules.

The remainder of this paper is organized as follows. Section 2 reviews the related work. Section 3 presents the proposed process model, beginning with its design rationale and an overview of the development process, followed by a detailed description of each development phase and its associated activities. Finally, Section 4 summarizes the conclusions and outlines directions for future work.

2. Related Work

The development of AI Systems has traditionally been supported by methodologies that follow two complementary perspectives: Knowledge Engineering and data-driven analysis.

Knowledge Engineering methodologies, including CommonKADS [17], Buchanan [18], and IDEAL [19], provide systematic approaches for eliciting, modeling, and representing expert knowledge during system development. These methodologies define structured development lifecycles that facilitate the construction of Knowledge-Based Systems. However, they provide limited support for incorporating data analysis and Machine Learning techniques into the development process. Conversely, Data-Driven methodologies such as KDD [20], CRISP-DM [21], SEMMA [22], and P3TQ [23] focus on data understanding, preparation, modeling, and knowledge discovery. Although some of these methodologies consider domain understanding during the initial project stages, they do not explicitly define mechanisms for systematically incorporating expert knowledge throughout the analytical process. More recently, [24, 25] proposed an adaptation of CRISP-DM to strengthen the participation of domain experts during project planning, data acquisition, and validation activities. Although this extension improves the interaction between domain experts and data scientists, it remains primarily data-oriented and assumes the availability of structured and standardized datasets, which is not always feasible. To compare existing methodologies, six methodological dimensions were selected because they represent the fundamental capabilities required for developing AI-enabled Decision Support Systems. Together, these dimensions cover the activities required to integrate expert knowledge with data-driven analysis throughout the development lifecycle, while also considering regulatory traceability. Specifically, the comparison considers knowledge acquisition, knowledge representation, data analysis, expert involvement, knowledge–data integration, and regulatory traceability. Table 1 summarizes how Knowledge Engineering and Data-Driven methodologies address each of these dimensions. The comparison is conducted at the level of methodological families rather than individual methods. It summarizes their predominant orientation and does not imply that all methodologies within each family address these dimensions uniformly.

Table 1
Comparison of Methodological Families.

Dimensions	Knowledge Engineering Methodologies	Data-Driven Methodologies
Knowledge Acquisition	Explicitly addressed through structured elicitation activities involving domain experts.	Considered only during the initial understanding of the problem domain.
Knowledge Representation	Explicit mechanisms are provided for modeling and formalizing domain knowledge.	Knowledge representation is not explicitly addressed.
Data Analysis	Limited support for data preparation and analytical tasks.	Comprehensive support for data preparation, modeling, and evaluation.
Expert Involvement	Continuous collaboration with domain experts is a fundamental component of the methodology.	Expert participation is generally concentrated in initial business understanding and final validation activities.
Regulatory Traceability	Not explicitly addressed.	Not explicitly addressed.
Knowledge-Data Integration	Machine Learning techniques are not explicitly incorporated.	Machine Learning is emphasized, but expert knowledge is only partially integrated.

The proposed process model addresses these limitations by combining the explicit knowledge acquisition and representation mechanisms characteristic of Knowledge Engineering with systematic data

analysis, continuous expert participation, knowledge–data integration, and regulatory traceability.

3. Proposed Process Model

This section presents the proposed process model. Section 3.1 introduces the design rationale underlying the proposed process model, explaining the reasoning behind its overall structure. Section 3.2 then describes the development phases and their traceability to the relevant standards.

3.1. Design Rationale

The model is organized according to four complementary design principles. The design principles were derived from the gaps identified in the comparative analysis and from the requirements established by the selected regulatory and standardization frameworks. The lack of systematic knowledge–data integration motivated the first principle; the absence of regulatory support motivated continuous traceability; the need to maintain consistency among knowledge artifacts motivated progressive knowledge evolution; and the transparency and human oversight requirements motivated explainability by design:

- **Integrated Knowledge Engineering and Data-Driven Analysis:** The proposed model promotes the coordinated use of Knowledge Engineering and data-driven analysis throughout the development lifecycle. Rather than treating symbolic and data-driven approaches as independent alternatives, both are considered complementary sources of knowledge that progressively contribute to the construction of the DSS. Accordingly, the process incorporates activities for expert knowledge elicitation, knowledge formalization, data-driven analysis, and hypothesis generation within a unified methodological framework.
- **Continuous Regulatory Traceability:** Regulatory requirements derived from the EU Artificial Intelligence Act and the selected ISO/IEC standards are therefore distributed across the development lifecycle [26], allowing development activities, generated artifacts, and regulatory obligations to remain continuously traceable, thereby supporting the development of trustworthy, human-centric AI-enabled DSS. This approach allows regulatory alignment and traceability to be addressed throughout development rather than deferred to a final verification stage.
- **Progressive Knowledge Evolution:** Knowledge is progressively refined throughout the development process. Initial domain knowledge elicited from experts is gradually transformed into increasingly formal representations, including glossaries, knowledge maps, ontologies, and reasoning rules. This progressive evolution promotes consistency among knowledge artifacts while enabling their refinement as domain understanding increases during the project.
- **Explainability by Design:** Explainability is incorporated from the earliest stages of the development lifecycle. By emphasizing explicit knowledge acquisition, structured knowledge representation, and transparent reasoning mechanisms, the proposed process facilitates the development of DSS whose recommendations can be understood, validated, and maintained by domain experts.

Collectively, these design principles define the rationale underlying the proposed process model and are reflected throughout its five development phases. The model adopts an artifact-oriented organization in which each activity produces explicit outputs that become inputs to subsequent activities, thereby supporting traceability, documentation, and knowledge evolution throughout the development lifecycle. The following section describes each development phase and illustrates how the proposed process model supports the systematic development of AI-enabled DSS while maintaining alignment with the EU AI Act and the selected ISO/IEC standards.

3.2. Process Model Description

The proposed process model is framed within the concept of a project, which the Project Management Institute defines as *"a temporary endeavor undertaken to create a unique product, service, or result"* [27].

A project has a well-defined scope, as it is carried out to achieve specific objectives and produce a clearly identified outcome. It is considered temporary because it has a defined start and end date. In the context of the proposed approach, the ultimate objective of the project is the implementation of a Decision Support System. Since the resulting artifact is a software system, the proposed process model can be operationalized within iterative and incremental software development frameworks. In the current instantiation, the Scrum framework for Agile Software Development [28] was adopted to organize project execution, facilitate collaboration among team members, and support continuous stakeholder involvement throughout the development process. Agile documentation typically consists of lightweight documents, diagrams, and templates that support communication and decision-making during project execution [29].

The proposed process model is not intended to replace the frameworks established by the ISO/IEC standards. ISO/IEC 22989 provides the conceptual terminology used throughout the model; ISO/IEC 23053 informs the organization of data- and ML-related activities; and ISO/IEC 5392 provides a reference architecture and activities associated with Knowledge Engineering. The process is organized as follows:

- **Project Definition:** This phase corresponds to the Inception process defined in ISO/IEC 22989 and aims to establish the purpose and intended use of the Decision Support System while considering the definition of an AI system provided by the European Union Artificial Intelligence Act. Accordingly, the project objectives are specified by identifying the organizational need that motivates the development of the system. In addition, the initial project characteristics are documented, including stakeholder identification, the available data repositories, and the participation of domain experts who contribute their expertise to the analysis. This phase lays the foundation for the entire project by ensuring a clear definition of objectives, a thorough understanding of the problem, and the identification of the key stakeholders and available data sources.
- **Domain Survey:** This phase focuses on defining the project scope and identifying its constraints, while decomposing the problem domain using cognitive knowledge maps.
- **Data and Knowledge Exploitation:** This phase involves a comprehensive exploration of both the available domain data and the knowledge contributed by domain experts. From a data perspective, the objective is to analyze the existing data repositories and transform them into a heterogeneous repository containing usable data. From a knowledge perspective, this phase supports knowledge acquisition through techniques such as interviews, protocol analysis, and repertory grid, as well as the construction of knowledge representation models, including conceptual models, ontologies, and knowledge maps, using Knowledge Engineering techniques. Its primary objective is to contrast and establish hypotheses between data and expert knowledge, thereby promoting a comprehensive understanding of the domain. This is the core phase of the proposed process model, as it integrates the frameworks defined in ISO/IEC 23053 and ISO/IEC 5392 while strengthening the combination of Knowledge Engineering and Machine Learning.
- **Intelligent System Specification:** This phase addresses the design of the AI system by defining the approximate reasoning models employed by the inference engine and encoding the rules contained within the knowledge base.
- **Intelligent System Implementation:** This final phase focuses on building and deploying the proposed solution through the implementation of the AI System. Once implemented, the system undergoes a comprehensive evaluation process that includes validation, verification, and assessments of usability, utility, and performance. This phase addresses system deployment and evaluation against the applicable requirements, documented criteria, and expected performance within the intended operational environment.

In the proposed process, the term Intelligent System refers to the AI-enabled DSS resulting from the specification and implementation phases. Table 2 presents the traceability between the phases of the proposed process model, the relevant articles of the European Union Artificial Intelligence Act, and the corresponding ISO/IEC standards. Certain requirements, such as risk management and transparency,

are considered cross-cutting concerns and are progressively refined throughout the different phases of the proposed model as part of its iterative development lifecycle.

Table 2

Mapping of Model Phases to Regulatory and Standard Frameworks.

Phase	AI Act Articles	Associated ISO/IEC Standards	Key Regulatory and Standardization Concerns Addressed
Project Definition	Art. 6	ISO/IEC 22989	Definition of project objectives, context of use, stakeholder identification, and preliminary assessment of regulatory applicability.
Domain Survey	Art. 6, 9	ISO/IEC 22989 ISO/IEC 5392	Definition of project scope, initial risk analysis, and development of preliminary knowledge maps.
Data and Knowledge Exploitation	Art. 10	ISO/IEC 22989 ISO/IEC 23053 ISO/IEC 5392	Integration of Knowledge Engineering and data-driven analysis, including Machine Learning techniques when applicable, to support system quality.
Intelligent System Specification	Art. 11, 13, 14	ISO/IEC 22989	Definition of reasoning models and preparation of technical documentation.
Intelligent System Specification	Art. 13, 14, 15	ISO/IEC 22989	System implementation, validation, verification, and compliance-oriented assessment.

The following subsections describe the activities associated with each phase of the proposed process model, together with their corresponding input and output artifacts.

3.3. Second Phase of Domain Survey

The objective of the first phase is to establish a clear and shared understanding of the purpose, context, and initial conditions of the Decision Support System to be developed. During the Project Definition phase, the definition of project objectives, context of use, and identification of stakeholders provide the basis for assessing the applicability of the regulatory requirements established by the AI Act. This phase comprises two main activities: “Project Objective Description” and “Identification of Initial Project Characteristics”. Table 3 summarizes the input and output artifacts associated with each of these activities.

Table 3

Activities of the Project Definition Phase.

Activities	Input Artifacts	Output Artifacts
Project Objective Description	Project Kick-off Meeting	Kickoff Dashboard (section Project Overview).
Identification of Initial Project Characteristics	Project Kick-off Meeting	Kickoff Dashboard (section Roles and Responsibilities and section Data Repositories).

The “Project Objective Description” activity consists of the project’s initial conceptual meeting, whose purpose is to establish a shared understanding of the overall project objective, the problem context, and the project participants. During this activity, the Project Kick-off meeting is conducted in accordance with the Scrum framework [28]. Participants collaboratively define the intended purpose of the system, identify the organizational need to be addressed, and determine the project’s key stakeholders. While the first activity focuses on establishing the project’s objectives and context, the second activity, “Identification of Initial Project Characteristics”, builds upon the outcomes of the initial meeting and focuses on documenting the project’s initial characteristics. During this activity, the complete project team is identified, and the corresponding roles and responsibilities are assigned. In

addition, the available data repositories within the application domain are identified and documented. The initial project characteristics also provide the information required to document a preliminary assessment of the AI Act applicability according to the system’s intended purpose and context of use. This preliminary assessment is documented as part of the Kickoff Dashboard.

3.4. Third Phase of Data and Knowledge Exploitation

The objective of the second phase is to achieve a deeper understanding of the system’s application domain by defining the project scope and decomposing the elements of the problem to be addressed. This phase provides a conceptual structure of the domain and establishes the foundation for the subsequent integration of data and knowledge. It comprises two main activities: “Project Scope Identification” and “Domain Element Decomposition”. Table 4 summarizes the input and output artifacts associated with each of these activities.

Table 4

Activities of the Domain Survey Phase.

Activities	Input Artifacts	Output Artifacts
Project Scope Identification	Project Kick-off Meeting	Kickoff Dashboard (section Project Scope)
Domain Element Decomposition	Initial Interview with Domain Experts	Initial Domain Cognitive Knowledge Map.

The “Project Scope Identification” activity focuses on the explicit definition of the project scope, including the expected deliverables, acceptance criteria, project exclusions, and the underlying assumptions. Based on the information gathered during the previous phase, a project board is created to consolidate these elements and ensure that all project participants share a common understanding of the system’s objectives and boundaries. In contrast, the “Domain Element Decomposition” activity aims to analyze and decompose the fundamental elements of the application domain through the application of Knowledge Engineering techniques. Based on the initial interviews conducted with domain experts, the key concepts and relationships that characterize the domain are identified. This information is then used to construct an initial cognitive knowledge map of the domain at an early stage of the project. A cognitive knowledge map is a structured representation of the experts’ mental model, capturing the knowledge derived from their experience and professional judgment. This type of representation enables knowledge to be structured by capturing both the domain context and the complex relationships among its key concepts. In a cognitive knowledge map, nodes represent the main concepts, whereas links represent the relationships perceived by the experts, reflecting their interpretations and underlying assumptions [30]. According to ISO/IEC 5392, a cognitive knowledge map constitutes a conceptual model, defined as a *“description of common concepts and their relationships, particularly to facilitate exchange of information between parties within a specific domain”*.

This initial conceptual representation establishes the basis for the progressive refinement of domain knowledge during the subsequent Knowledge Exploitation phase.

3.5. First Phase of Project Definition

This phase operationalizes the integration between Knowledge Engineering and data-driven analysis introduced in the Design Rationale. The objective of the third phase is to integrate the available data with expert knowledge in order to develop a comprehensive understanding of the domain aspects to be modeled. This phase constitutes the core of the proposed process model, as it brings together data-driven analysis and Knowledge Engineering approaches, thereby establishing the foundation for the design of the Decision Support System’s reasoning models. It comprises two complementary subphases: “Data Exploitation” (section 3.5.1) and “Knowledge Exploitation” (Section 3.5.2). Both subphases are carried out iteratively and in parallel, converging into a central integration process through which hypotheses are contrasted, validated, and refined (3.5.3). Table 5 summarizes the input and output artifacts associated

with each subphase and activity, whereas Figure 1 illustrates the iterative interaction between both subphases together with the progressive evolution of the corresponding knowledge artifacts.

Table 5
Activities of the Data and Knowledge Exploitation Phase.

Subphase	Activities	Input Artifacts	Output Artifacts
Data Exploitation	Data Preparation	Data Repositories	Prepared Data
	Data Integration	Prepared Data	Data Lake
	Data Exploration	Data Lake	Data Analysis Results
Knowledge Exploration	Knowledge Acquisition	Interviews with Domain Experts Initial Domain Cognitive Knowledge Map (result phase of Domain Survey)	Documented Domain Knowledge
	Knowledge Conceptualization	Documented Domain Knowledge	Domain Glossary Domain Cognitive Knowledge Map
	Knowledge Representation	Domain Cognitive Knowledge Map	Domain Ontology
Cross-Cutting	Hypothesis Validation	Data Analysis Results Documented Domain Knowledge	Refined Domain Knowledge (updated versions of the Ontology and Cognitive Knowledge Map) Hypothesis Validation Register

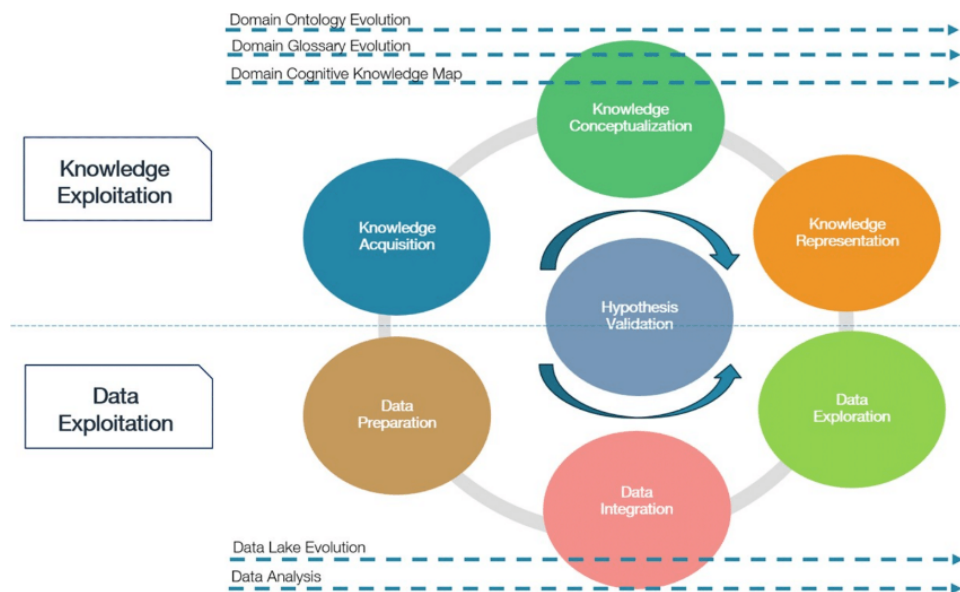


Figure 1: Integration of Data and Knowledge Exploitation.

3.5.1. Subphase of Data Exploitation

The Data Exploitation subphase focuses on the analysis, preparation, and integration of the available data repositories within the domain in order to perform data-driven analysis, including the application of Machine Learning techniques when appropriate. This subphase comprises the activities of “Data Preparation”, “Data Integration”, and “Data Exploration”, whose objective is to transform raw data

into prepared, integrated, and analytically usable resources for the project. Following the analysis and preparation of the data, the Data Integration activity consolidates the identified repositories into an integrated data environment, such as a Data Lake, preserving the traceability of the data sources and facilitating the joint analysis of heterogeneous information. Finally, the Data Exploration activity enables the identification of relevant patterns and trends through exploratory analyses, generating empirical evidence that contributes to a deeper understanding of the domain. Depending on the application domain, data analysis may incorporate Machine Learning techniques such as clustering, classification, association rule mining, or anomaly detection to identify patterns and generate hypotheses. When applicable, data preparation and exploration activities also consider dataset provenance, quality, relevance, representativeness, and potential sources of bias in order to support reliable data analysis and, when applicable, data-driven model development.

3.5.2. Subphase of Knowledge Exploitation

The Knowledge Exploitation subphase focuses on the acquisition, conceptualization, and representation of domain knowledge through techniques from Knowledge Engineering. This knowledge is progressively formalized through different artifacts, such as glossaries of terms, conceptual models, ontologies, and cognitive knowledge maps, which evolve throughout the phase as the understanding of the domain deepens. In this way, the experts' private and tacit knowledge is transformed into explicit and reusable representations. The outcome is a set of progressively structured and formalized representations of domain knowledge, validated by the experts, that provide a structured and explainable view of the problem. In the "Knowledge Acquisition" activity, relevant concepts, relationships, and reasoning patterns of the domain are identified through expert interviews, protocol analysis, and other knowledge elicitation techniques. Knowledge elicitation techniques can be classified as direct or indirect [31]. Direct techniques involve asking questions directly to the individuals involved and include Interviews [32, 33], Questionnaires [34, 35], and Surveys [36]. Indirect techniques, on the other hand, obtain knowledge through observations previously performed or recorded, and include Observation of Routine Tasks [19], Repertory Grid, and Protocol Analysis. The Repertory Grid technique, defined by psychologist George Kelly in [37], is based on Personal Construct Theory. According to the Royal Spanish Academy (RAE), a construct is a "bipolar descriptive category" used by individuals to organize "data and experiences of their world". Kelly defines constructs as a way in which two or more things are perceived as similar and therefore different from a third or fourth element [38]. In this sense, personal constructs are characteristics of objects or elements that allow individuals to make judgments [39] and interpret the world around them [40]. The Repertory Grid method applies these bipolar characteristics to generate a structured representation of the mental model through which a person distinguishes between similar and different elements [41]. By processing subjective data through simple operations, this technique aims to go "beyond words" in representing expert knowledge. Since domain experts often feel more comfortable and precise when using their own terminology, the Repertory Grid allows knowledge to be acquired in a more natural and flexible way than many other techniques [39]. Furthermore, because the grid structure can be applied to a wide range of topics, it enables knowledge acquisition across diverse areas. Finally, the Protocol Analysis technique is based on the procedure defined by Ericsson and Simon [42], which uses verbal protocols to obtain individual accounts of a person's cognitive processes during the execution of a task or while recalling it [43]. According to Ericsson, protocol analysis is a valid data collection method that enables the elicitation of verbal reports reflecting sequences of thoughts. Originally introduced in psychology, this technique involves analyzing the verbalization produced by an individual while performing a task, with minimal interaction from the researcher. The verbalizations are recorded and later transcribed verbatim, producing a verbal protocol that represents a report of the individual's conscious mental processes. During task execution, the individual verbalizes or "thinks aloud," allowing the researcher to capture a recorded account of their reasoning process. The resulting transcription is then analyzed qualitatively to identify the knowledge underlying the performed activity. In this context, Protocol Analysis has been adopted within Artificial Intelligence as a technique for uncovering expert knowledge in specific domains, where experts are asked to think

aloud while performing a task. Protocol Analysis is useful for obtaining information about procedures used by experts during problem-solving that they are nevertheless unable to explain explicitly.

The “Knowledge Conceptualization” activity enables the organization of the acquired knowledge in order to facilitate the understanding of the domain and the terminology used. It allows the construction of a mental map of the application domain using a glossary of terms and a cognitive map of domain knowledge. The glossary of terms is a structured list that includes all relevant domain terms (concepts, characteristics, and values), their descriptions in natural language, as well as their antonyms and synonyms. It is used to standardize the language employed within the project and to ensure that all participants share a clear understanding of the meaning of these terms [31, 19]. According to [44], glossaries of terms play a fundamental role in project management, as they constitute a valuable communication tool. Ineffective communication may lead to project failure or significant time losses; therefore, a precisely defined glossary ensures that project deliverables are developed according to consistent definitions and meet the project requirements.

Finally, in the “Knowledge Representation” activity, the representations developed in the previous activity are formalized through a domain ontology, which explicitly describes the semantic relationships and inference processes involved in decision-making. In the field of Knowledge Engineering, an ontology is an artifact used to formalize domain knowledge. In this context, the most widely accepted definition is that proposed by [45], which describes an ontology as “*a formal and explicit specification of a shared conceptualization*”. In this definition, conceptualization refers to an abstract and simplified representation of what individuals know about a subject or the world in general; explicit indicates that it is described in a specific language; formal means that it can be interpreted by a machine; and shared implies that the captured knowledge reflects a consensus within the community regarding the domain [46]. For the construction of the ontology, the Methontology methodology [47] is adopted, as it provides a well-established framework for developing ontologies based on previously conceptualized knowledge. This methodology is particularly suitable because it follows an iterative process based on evolutionary prototypes and comprises four phases: specification, conceptualization, formalization, and implementation. Moreover, it facilitates the integration of previously developed knowledge artifacts, such as those produced in earlier activities, enabling a transition from conceptual models to formal representations.

3.5.3. Subphase of Hypothesis Validation

The Hypothesis Validation subphase represents a central process within the Data and Knowledge Exploitation phase, as it enables the comparison and validation of hypotheses derived from both data analysis and expert knowledge, together with the refinement of the resulting conceptual knowledge. As a result of this subphase, the hypotheses generated from data analysis and expert knowledge are systematically assessed and documented. The validated hypotheses contribute to the refinement and updating of the ontology and the cognitive knowledge map. The Hypothesis Validation Register is produced to record the hypotheses together with their supporting evidence and validation outcomes. This register includes each hypothesis, its source, the evidence used during the validation process, and the corresponding validation outcome, as illustrated in Table 6.

When the available evidence is insufficient or contradictory, the hypothesis remains open for further analysis and is recorded as requiring further investigation. Hypotheses requiring further investigation are reassessed during subsequent iterations of the Data and Knowledge Exploitation phase as additional evidence or expert knowledge becomes available. The refined knowledge artifacts produced during this phase, particularly the updated domain ontology and cognitive knowledge map, together with the Hypothesis Validation Register, provide the foundation for the formal specification of the reasoning model in the next phase.

Table 6
Hypothesis Validation Register.

ID	Hypothesis	Source	Evidence	Outcome
<Hn>	<statement describing the proposed relationship or assumption>	< Data Analysis / Domain Knowledge / Data Analysis + Domain Knowledge >	< empirical evidence, expert knowledge, or both used to assess the hypothesis>	<validated by expert knowledge / validated by data / validated by expert knowledge and data / requires further investigation / not validated>

3.6. Fourth Phase of Intelligent System Specification

The fourth phase aims to formally specify the behavior of the Decision Support System. This phase transforms the conceptual knowledge acquired during the previous phases into an explicit reasoning model, thereby preserving the explainability and traceability principles introduced in Section 3.1. The proposed approach adopts a fuzzy inference engine, as it enables expert reasoning to be effectively modeled in complex domains characterized by uncertainty and imprecision. Since the introduction of fuzzy sets [48], Fuzzy Logic has been widely applied to represent vague, ambiguous, imprecise, noisy, or incomplete information in complex decision-making processes [49, 50]. Fuzzy inference systems, such as the Mamdani model [51] and the Takagi–Sugeno model [52], represent expert knowledge through linguistic rules and provide an appropriate reasoning mechanism when the application domain cannot be described using rigid thresholds. The selection between Mamdani, Takagi–Sugeno, or another fuzzy inference model depends on the required interpretability, output characteristics, and domain constraints. Accordingly, this phase comprises two main activities: “Knowledge Base Specification” and “Approximate Reasoning Model Definition”. Table 7 summarizes the input and output artifacts associated with each activity.

Table 7
Activities of the Intelligent System Specification.

Activities	Input Artifacts	Output Artifacts
Knowledge Base Specification	Domain Cognitive Knowledge Map Domain Ontology	Fuzzy Reasoning Rules
Approximate Reasoning Model Definition	Fuzzy Reasoning Rules	Selected Reasoning Model

The “Knowledge Base Specification” activity is responsible for defining the reasoning rules that will be stored in the knowledge base. Based on the ontology and the cognitive knowledge map, the domain concepts relevant to decision-making are identified. Since Fuzzy Logic [53] is employed, membership functions are defined for each concept together with their corresponding linguistic terms (e.g., low, moderate, high), according to the expert knowledge of the domain. Subsequently, fuzzy reasoning rules are defined in the IF–THEN form.

On the other hand, the “Approximate Reasoning Model Definition” activity aims to define the reasoning mechanism of the inference engine in order to support decision-making. In addition, the fuzzy rules defined in the previous activity are adapted and formalized according to the selected inference model. The result of this activity is the complete specification of the approximate reasoning model, which explicitly describes how the system combines the knowledge stored in the knowledge base and manages uncertainty in order to generate appropriate inferences.

3.7. Fifth Phase of Intelligent System Implementation

The fifth and final phase of the proposed process model focuses on the implementation of the Fuzzy Logic-based Decision Support System. During this phase, the fuzzy reasoning rules defined in the previous phase are translated into an executable system capable of processing domain data and generating inferences consistent with expert knowledge. This phase comprises two main activities: “System Development” and “System Validation and Evaluation”. Table 88 summarizes the input and output artifacts associated with each activity.

Table 8

Activities of the Intelligent System Implementation.

Activities	Input Artifacts	Output Artifacts
System Development	Fuzzy Reasoning	Implemented Intelligent System
	Rules	
	Selected Reasoning Model	
System Validation and Evaluation	Implemented Intelligent System	Validation Results Expert Feedback Report
	Defined Acceptance Criteria (result of the Domain Survey phase)	
	Case Data	
	Expert Decisions	

The “System Development” activity focuses on implementing the selected fuzzy inference engine using the reasoning rules defined in the previous phase. During this activity, the membership functions corresponding to each linguistic variable, together with the IF–THEN rules that encode expert knowledge, are implemented to produce an operational Decision Support System. Once the system has been implemented, the “System Validation and Evaluation” activity assesses the resulting system through testing with a representative set of cases from the application domain. The validation process verifies that the system’s outputs are consistent with the expectations of the domain experts and evaluates whether the acceptance criteria defined during the Domain Survey phase of the process have been satisfied. In addition, this activity provides an opportunity to identify potential improvements and refinements. Since the proposed solution is designed as a decision support tool rather than an autonomous decision-making mechanism, its use is intended to remain under the supervision of qualified professionals. The validation process also identifies the points at which human review, confirmation, or override is required before the system recommendation is acted upon. Evaluation criteria may include agreement with expert decisions, predictive or classification performance when applicable, usability, utility, robustness, and consistency of explanations. Beyond defining the reasoning model, the artifacts produced during the Intelligent System Specification and Intelligent System Implementation phases contribute to the traceability and documentation required to support transparency and human oversight throughout the development lifecycle.

4. Conclusion

This paper proposes a process model for the development of Artificial Intelligence (AI)-enabled Decision Support Systems (DSS) that integrates Knowledge Engineering with data-driven analysis, including Machine Learning techniques when applicable, within a structured methodological framework. The

proposed model is organized into five development phases covering the entire lifecycle, from project definition to system implementation, while providing traceability to selected provisions of the European Union Artificial Intelligence Act and the frameworks established by ISO/IEC 22989, ISO/IEC 23053, and ISO/IEC 5392. Its application supports the development of Decision Support Systems based on fuzzy inference models capable of managing the uncertainty inherent in human decision-making.

Unlike existing methodological families, which primarily emphasize either Knowledge Engineering or data-driven analysis, the proposed process model coordinates expert knowledge elicitation, data analysis, hypothesis validation, and reasoning model specification within a unified artifact-oriented lifecycle. This integration enables hypotheses derived from data to be contrasted with expert knowledge, facilitating the progressive refinement of knowledge artifacts while supporting explainability, traceability, and transparency throughout the development process. Consequently, the proposed model provides methodological guidance for multidisciplinary teams involved in the development of AI-enabled Decision Support Systems.

The proposed process model has been instantiated in the development of a clinical DSS. Since the objective of this paper is to present and justify the methodological framework, the detailed application of the process and its empirical evaluation fall outside the scope of this paper.

The proposal currently has three main limitations. First, the process has so far been instantiated only in a clinical setting, and its generalizability to other application domains remains to be examined. Second, the process requires sustained participation from domain experts, which may affect its feasibility in contexts with limited expert availability. Third, although the model provides traceability to selected provisions of the EU AI Act and ISO/IEC standards, it should not be interpreted as a complete conformity assessment framework.

Future work includes applying the proposed process model to additional application domains, evaluating its generalizability beyond clinical DSS, and performing empirical studies to assess its effectiveness and practical applicability in different organizational contexts.

Declaration on Generative AI

During the preparation of this work, the authors used ChatGPT in order to: Text Translation. After using this tool, the authors reviewed and edited the content as needed and takes full responsibility for the publication's content.

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