From Simple Sandbox Process to Regulatory Sandbox Framework: Serving the Dual Objectives of AI Regulation

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In this paper, we build on a simplified process to evaluate AI systems compliance with AI Act. As AI Act's risk-based regulatory measures simultaneously strive for providing innovative, but trustworthy AI systems to the market, we extend the process to an AI Regulatory Sandbox Framework (AIRSF), which is connected with the EU's innovation ecosystem. The study builds on a design science approach combined with action research sandbox as a boundary object for multistakeholder sandbox development. We first analyse the options for regulating AI Systems. In doing so, we explore the regulatory sandbox as a means aiming to remedy the known limitations of regulatory sandboxes, especially from the viewpoint for SMEs . We conclude by reflecting upon the findings during the sandbox development process.

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1 Introduction

The European Union (EU) is seeking to boost the development and deployment of AI systems by attempting to strike a balance between innovation and regulation. One proposed mechanism for achieving this balance is the implementation of AI Regulatory Sandboxes to improve business viability and compliance, particularly with fundamental rights.

However, AI regulatory sandboxes are not a silver bullet to this end and multiple challenges currently stand. First, the AI Act's requirements to identify and mitigate risks to fundamental rights are often perceived as distant from the practical realities faced by of AI providers, deployers, and regulators (Orwat et al., 2024). In addition, the role of Regulatory Sandboxes remains unclear. Second, while the AI Act (AIA) mandates free access to supervision and testing environments for small and medium-sized enterprises (SMEs) and start-ups, supported by various EU and Member State innovation initiatives, this specific of their implementation is still evolving. Thirdly, whilst in introducing an AI System on the European Common Market is possible without sandbox participation, AI providers and deployers may expose themselves to non-compliance risks. For example, if they are unable to demonstrate adequate risk assessment and mitigation measures prior to market entry. Finally, the objectives of regulation seem contradictory (e.g., Lanamäki et al., 2024) and the practical deployment of sandboxes is still under deployment.

2 Research Questions and Method

The core research question underpinning this paper is: **should and could regulatory sandboxes be practically implemented for AI as a Europe-wide mechanism?** We divide this into further sub-questions:

- What does the AIA require from sandbox solutions to balance the promotion of innovative AI uses with compliance requirements?
- What factors must be considered in designing an attractive sandbox, particularly for SMEs?
- What insights have we gained during the development of such a process?

To elucidate these questions, we adopt a constructive research approach of design science research by van Aken and Romme, 2009). We aim to develop a generalizable design proposition to address the identified challenges in practice or identified in prior research when implementing AI regulatory sandboxes. The effectiveness of our proposed design solution will be evaluated over the course of our on-going project. During the project we engage a range of relevant experts, regulators, companies and vested parties in the co-designing of eventual sandbox.

Our intervention in the sandbox process is conceptualised as a Stage-Gate model (see e.g. Cooper, 1990), providing a modular process that allows for iterative incorporation of details, and connected services. Our Stage-Gate model serves as a shared design artefact to classify, evaluate and elaborate on risk factors associated with AI in use cases. Methodologically, our research approach integrates elements of Action Research with Design Science Research (Iivari and Venables, 2009), because the proposed solution design is adaptable to diverse AI implementation contexts, industries, and domains. (e.g. Buocz et al., 2023; Birkstedt et al., 2024; von Steffen, 2025), The purpose of our baseline process is to serve as a boundary object for further development of Sandbox in co-operation with various stakeholders.

3 Regulatory Approaches for AI Innovations

The EU has gained a reputation as the preeminent technological regulator, initially establishing regulation for unified internal digital markets before expanding to regulate international technology corporations to promote a more competitive internal market. This dual approach aims to foster innovation while simultaneously safeguarding user and worker rights and ensuring fair competition. The resulting landscape comprises complex set of overlapping and sometimes contradicting regulation that impact the operation of technology-driven companies by imposing constraints on data collection, processing and sharing practices, as well as on interactions with internet users, or businesses (Bradford, 2024).

Meanwhile, some have claimed the dominance of less restrictive AI policies in the United States, innovation-focused policies in China have cast a shadow over the European ideal of 'control-first, innovate-thereafter'. There are growing pressures (Draghi, 2024) to avoid what critics have deemed the confusing, contradicting over-regulation of the market and instead to boost AI-related innovations. In response,

the EU has established several innovation-fostering initiatives including the European Digital Innovation Hubs (EDIH), sectoral Testing and Experimentation Facilities (TEFs), and AI Factories, which are complemented by national business incubators and start-up ecosystems. These developments underscore the tension made evident by the introduction of the AIA: the question is no longer whether to regulate AI, but how to do so in balance with the initiatives and activities that support innovation.

One approach relies on leveraging voluntary *ethical principles* as an alternative to regulation, to complement sole business logic. However, as Buhmann and Fieseler (2021) illustrate, the opacity of AI makes obscure the decisions made by designers. As the laymen are not involved, they cannot determine the outcome before it is too late – they cannot afford to rely on designers' following voluntary ethical principles only. By implementing such principles, innovators are positioned as proactive representatives of public discourse, tasked with discovering to ethically sound solutions through responsible innovation processes. Concerns persist regarding whether they really can properly represent the perspectives of all stakeholders affected by the influence of an AI system (Brown and Pironka, 2021). The EU is not alone in its concerns that technology companies cannot fully foresee how their AI solutions might compromise individuals' fundamental rights or undermine established democratic institutions and practices. Indeed, the OECD AI policy observatory, reflects an emerging consensus that AI development prioritises societal benefit while ensuring equitable conditions for market actors and participants thereby justifying and necessitated coordinated global regulatory frameworks. (OECD, 2022).

Regulatory implementation varies depending on the underlying regulatory strategy (these are mutually exclusive), which may involve a) comprehensive overhauling updates to existing laws, b) creation of novel exclusive regulations, or c) engagement in experimental/incremental regulation (the category which the EU AIA belongs) (Sloane and Wüllhorst, 2025). The latter is characterised as *middle-out regulation* because it is positioned between conventional 'hard law' and industry self-regulation (Pagallo et al., 2019). In a middle-out approach, stakeholders engage in mutual learning and iterative adaption of the regulation. This approach is getting preferred by scholars for regulating rapidly evolving technology in society (e.g., Ranchordas, 2021).

Regulatory sandboxes are a primary means for implementing middle-out regulation and are gaining traction (Zetchse et al., 2017; Longo and Bagni, 2025) as general means to provide guidance for the development and testing of innovations under conditions isolated from the markets. Sandboxes have been used for these purposes since the financial crisis in FinTech (e.g., Zetsche et al., 2017) and for evaluating compliance with privacy regulation (GDPR).

According to Sloane and Wüllhorst (2025), Dardykina (2024), and Seferi's (2025) analyses, contemporary sandboxes are implemented in various ways. At their core, regulatory sandboxes are defined as *"a controlled framework established by a competent authority in which participants – whether public or private – can develop, validate, and test innovative products under regulatory supervision for a limited period of time"* (Longo and Bagni, 2025, p. 28). However, initial implementation has demonstrated a *"The regulatory sandbox alone as presently structured is typically too limited in scope and scale to promote further meaningful innovation"* (Zetsche et al., 2017; c.f. Dardykina, 2024, p. 4), providing the motivation for our research.

Therefore, addressing our second research question, we analyze whether a sandbox suits our situation. Recent AI regulatory sandbox trials (Truby et al., 2022; Buocz, 2023; von Steffen, 2025), have found the main challenge for AIA sandboxes centred around access to the sandbox and the dual objectives of fostering innovation while ensuring regulatory compliance. Frameworks for balancing these goals have been proposed (e.g. Janssen et al., 2022; Baldini and Frances, 2024), as well as software tools (OECD, 2022). As Trusby notes: "… *it [a sandbox] exposes the developer to compliance and setup costs, an added layer of regulatory supervision, and it exposes the AI technology to regulators and third parties. In exchange for these risks, a regulatory sandbox should minimise regulatory constraints, lower the risk of regulatory enforcement and liability and provide ongoing guidance from regulators."* (Truby, 2021, p. 291). At present, it remains uncertain whether this intended mutual exchange of value will materialize.

Nevertheless, AIA act requires the duality of balance. Díaz-Rodríguez et al. (2024) propose an ideal for trustworthy AI by dividing regulatory actions to *ex ante* evaluation and *ex post* Market Surveillance for meeting the dual objectives. Their drafted procedure leaves many questions open for practical implementation, such as when is the system ready for compliance evaluation? What if it gets rejected, can it return some day after further development and revision? What if there are domain

specific regulations to be considered beyond AI Act requirements? Can an AI System candidate be altered to meet the requirements while in the sandbox?

Considering the AIA's objectives, we argue greater attention should be paid to sandboxes as enablers for improving AI systems' market viability. To this end, sandboxes should relate to broader innovation support ecosystems such as funding programmes, peer support and expert guidance to provide varied forms of compliance evidence, especially from the National Supervisory Authorities.

3.2 Special Requirements of SMEs

Our understanding of the needs of SMEs for the features of sandboxes emerge from both the literature and through our collaboration with authorities and experts. Despite the well-intentioned initiatives of the AIA, SMEs often struggle to adopt or create AI innovations due to the rapidly evolving regulatory environment, complex and inconsistent policies, and the serious legal consequences of non-compliance (Muminova et al., 2024; Ardito et al. (2025)). These challenges are burdensome for SMEs because they typically work with limited legal and administrative resources (Iyelolu et al., 2024; Wolf-Brenner et al., 2024; Timan et al., 2021).

Over half of European SMEs have reported they view regulation and administrative obligations among top challenges to their business (EC, 2020). Regulatory sandbox has been proposed as a potential solution because they encourage mutual learning between regulators and AI providers (Moraes, 2024). In addition to reducing regulatory uncertainty, sandboxes could also aid SMEs by connecting them with financiers and funding sources (Muminova et al., 2024). Regulatory sandboxes include valuable information about regulatory risks and requirements, too (OECD, 2023.)

However, for SMEs reap these benefits, they must be made aware of their potential value, and information about how they are to be provided. Indeed, there is a risk that SMEs may lack knowledge of regulation and an understanding of how related sandbox processes work, which could deter participation.

In turn, if sandboxes are to fulfil their proposed value, the issue of sandbox capacity should be solved. Indeed, there is concern stemming from the potential limited capacity of sandboxes to accommodate the volume of potential users. There are over 20 million entrepreneurs in Europe and even if 10% are involved in AI development or application, the scale of demand would be significant. These potential numbers highlight the need for the sandbox process to be streamlined, scalable, and eventually digitalized to ensure the efficient handling of potential participation.

As such, an AI regulatory sandbox should be enhanced with analysis and testing capabilities. It should thus be designed to support interaction among internal and external stakeholders, while addressing the capacity challenges, potentially through a service desk and process automation. With the previously outlined considerations these bring to light three additional design requirements for an AI regulatory sandbox: simplicity, transparency, and efficiency.

Finally, it is important to note that the AIA mandates compliance evaluation (for high-risk AI Systems), but sandbox participation is voluntary. We argue this creates potential unintentional risk exposure for SMEs which may lack the resources to fully identify and address compliance issues outside the sandbox. Meanwhile, large companies can avoid this risk internally through established corporate governance structures and resources. They have additional incentives to invest in compliance for fear of negative reputation and sanctions (Birkstedt et al., 2024) without the need for sandboxes. Therefore, to attract and serve less resource-rich SMEs, sandboxes must offer similar value, such as guidance, compliance tools, access to funding and connections to support initiatives.

4 Baseline Sandbox Process as a Stage-Gate -Model

To support the practical implementation of AI regulatory sandboxes, we propose a simple baseline process. This effort is motivated by the need to avoid the common pitfalls identified in above. To define the scope, the borders, interfaces and design the functions of AI Sandbox, the following design requirements must be addressed. These will be validated against our ongoing EU-wide survey results:

1. Eligibility Criteria: clear and consistent criteria are needed to determine which AI systems, providers, and deployers can participate in the sandbox. This has been a challenge in past sandbox implementations (Dardykina, 2024; von Steffen, 2025).
2. Integration with innovation ecosystems: the sandboxes should be connected with the innovation ecosystems to assist in peer support, expert advice and funding access (Draghi, 2024; Muminova et al., 2024).
3. Market access facilitation: the sandbox should support viable AI systems reach the market by providing expert validation and assistance in obtaining the necessary documentation for conformity registration and assessment (AIA objective).
4. Regulatory Engagement: Guidance from and interactions with National Supervisory (NSAs) and Competent Authorities (NCAs) to comply with the AIA and related regulations. (AIA requirement for the competent authorities).
5. Re-entry Criteria: criteria must be established for rejected or suspended AI systems to re-enter the compliance evaluation processes after necessary revisions (our on-going discussion with authorities and providers).
6. Iterative flexibility: guidelines should specify when and how the original AI system can be altered during sandbox participation. (to be discussed with the authorities, consultants and providers).
7. Procedural aspects: the sandbox process should be transparent, predictable, simple, cost-efficient with the ultimate aim to reduce time to market (conclusions by the researchers).

As the above requirements are intertwined, we identify the need is to provide initial guidelines and transparent steps for AI providers. Just as importantly, the sandbox should be communicated and developed as a shared artefact so that EU innovation ecosystem stakeholders, NCAs, NSAs, industry and domain experts, AI developers and deployers can build a shared understanding to assess and articulate how sandboxes can facilitate the journey from concept to candidate AI system. This is done through compliance evaluation, leading finally to the successful registration and market entry of CE-marked, trustworthy and innovative AI System for the market.

4.1 Getting prepared for sandbox

The process of an AI System's sandbox participation starts with self-evaluation by the AI provider leading towards entry gate. This involves documenting whether the AI system meets the practices in their intended context environment, i.e. its use cases and whether it initially complies with AI Act. If there is uncertainty regarding compliance, an AI system becomes a candidate for evaluation, and is lead towards industry specific, domain specific, or general evaluation of compliance (see fig. 1). The first stage is therefore to identify the AI system's core use case and determine the scope of its intended application.

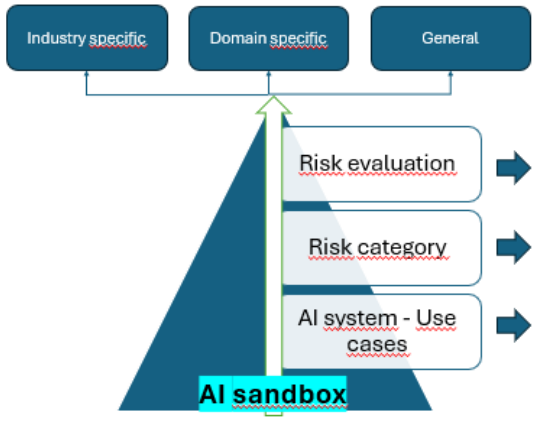

Figure 1: AI Sandbox process builds up from the bottom

Use cases can be assessed along two key dimensions:

- *Number of AI models/systems:* The number of AI models/systems deployed significantly influences the effort required to evaluate compliance. Different models within the AI system may fall into distinct risk categories, and when multiple models are used, each may require distinct evaluation methods (e.g. OECD's evaluation tools).
- *Use Across Domains /Industries:* Deploying an AI System across different domains or industries increases the need for regulatory scrutiny for each domain/industry. Each domain may be governed by sector-specific rules and standards. Our estimations suggest applying an AI system across multiple domains could double the effort required for compliance due to

the need for replicated evaluation processes. These two sets of use cases span the following matrix.

The initial division is explained in Appendix 1. It is of use in estimating the readiness and effort required for successful compliance evaluation. Thus, whenever a system involves multiple risk categories it should undergo scrutiny through participation in the AI sandbox.

4.2 The process

The actual sandbox process begins with the registration of the AI-system candidate (e.g., EU unique *AI System identifier*, *case process #, NCA-id,* and *applicant id*) and documentation for classification and related documentation (data sets, GDPR-compliance, AI model in use etc., see e.g. guidelines in (OECD, 2022). This information should be made publicly available or accessible among NCAs for two reasons. First, to prevent forum shopping/redundant sandboxing processes. Secondly, it signals the AI System as in the evaluation process (Zarra, 2025) for changed risk status, exit reports/declaration of conformity to enter to market - or halted evaluation.

The eligibility for sandbox entry depends on the AI system's maturity and its risk classification. Since the AIA refers to practices and use cases the AI system should be assess early to ensure whether it does not contradict with safety, livelihoods and rights of people making it *unacceptable to the market* independently of its use case. If the AI System passes this first stage, it should be evaluated for risk classification according to documentation requested by authorities (based on rules of conduct of AI Office) in the AI system's use case(s). If the eligibility criteria (proper documentation, and description of use cases) are met, AI Systems can be undergoing further scrutiny according to its preliminary risk category. If the AI system is *high risk,* it is subject to strict obligations including risk assessment and mitigation, quality of datasets, data logs, access to compliance assessment information, human oversight across all use cases. If the AI system is in the *limited risk category*, it is subject to disclosure obligations across all use cases. These initial stages (referred to as Gates 0 and 1) are depicted in the Stage-Gate model process flow (Fig. 2, in Appendix 2).

Accurate risk classification often requires further evaluation of the use cases, which may involve consultation with other sectoral authorities to supplement NCAs guidance (e.g. privacy, etc.). At this stage – Gate 2 it is likely necessary to engage with the innovation ecosystem to align its development with regulatory compliance (Janssen et al., 2022). If the use case specific evaluation reveals industry, or domain specific concerns, a more granular evaluation of the AI System would additionally be required (Gate 3). The specific use case(s) provide the basis for assessing the AI system's data, model and outputs, particularly focussing on their content and quality to pass Gates four and five. Special attention must be given to the full data lifecycle, intellectual property considerations, and the integration of data from various repositories used to generate the system's outputs. These stages may reveal potential non-compliant features in the candidate AI-systems. In such cases, we see there two potential remedies: first, introducing value-added services from the innovation ecosystem/consultants to address deficiencies in the data or model (Pagallo et al. 2019), or secondly, allowing some systemic uncertainty (Novelli et al., 2024) that can later be simulated in testing environments (Gate 6).

The goal of our tentative sandbox process is to ensure only a minority of AI system candidates will proceed to the final technical testing environment. Most evaluations should occur in the early stages of the sandbox through iterative learning and feedback (see Fig. 2, Appendix 2) to meet both the eligibility and compliance criteria outlined in the AIA. Only a smaller proportion of AI solutions are expected to progress to phase 2, which requires a more detailed risk analysis. At that stage, innovation ecosystem stakeholders can provide legal, technical and business support to help revise and improve the candidate AI system. While the final risk classification of the AI system will ultimately depend on the specific use case(s), quality of the data and models, the likelihood of achieving proof of compliance increases through the support from the innovation ecosystem and accumulated regulatory insights from NSAs and NCAs.

5 Considerations for Further Development

The proposed candidate AI systems are assisted through the process in collaboration with the existing EU AI innovation ecosystem. This process can be supplemented with mechanisms and tools for ethical and trustworthy AI assessment, many of

which are already available on international platforms such as OECD.AI[6] The tools can be adapted to align with the to the basic process stages of our framework.

To support the simultaneous and practical implementation of those two objectives, regulators could introduce a dedicated service desk. This service desk would manage sandbox operations but also serve as a function for the accumulation and dissemination of regulatory knowledge, which is important for ensuring the interoperability of sandboxes across member states. Also, the final report from sandbox process should be compatible between member state sandboxes and preferably utilise (Fig 2., Appendix 2) certificate levels to reflect how far a candidate AI system has progressed through the sandbox. These levels can serve as indicators during funding rounds, helping stakeholders assess the system's regulatory maturity and readiness.

6 Conclusion

In sum, this paper presents a baseline process for evaluating AI system compliance with the EU AIA, addressing critical gaps in the practical implementation of AI regulatory sandboxes, particularly for SMEs and start-ups that face challenges in navigating complex regulatory environments. The proposed sandbox process also addresses the "opacity problem" of AI systems previously outlined in Chapter 3 by systematically examining both data and algorithmic components within specific use contexts with stakeholders. By categorizing AI systems according to deployment complexity (single vs. multiple models) and application scope (single domain vs. cross-domain), we enable more accurate risk assessment and tailored regulatory scrutiny.

Furthermore, by extending the process baseline with its stage-gates to AI Regulatory Sandbox Framework (AIRSF) that balances dual objectives: enabling AI innovation while ensuring compliance with risk-based regulatory requirements. The AIRSF is designed to be linked directly with innovation ecosystem stakeholders and services, offering a structured pathway from early AI system development to market entry through clearly defined steps towards regulatory compliance and legal certainty. As a result, our framework overcomes several limitations identified in previous sandbox implementations by providing clear eligibility criteria, transparent evaluation steps, and graduated certification levels. The baseline process is designed to scale

efficiently, with most AI systems expected to reach to market readiness through early-stage support, while only complex or high-risk systems progress to a more comprehensive evaluation in later stages utilizing also the innovation ecosystems to full potential

The AIRSF can be supported, managed and utilised for regulatory learning through service desk-style mechanisms, but the final design is subject to further iterations with stakeholders in the design scientific sense and its actual implementation in the sense of action research by the actors. This will take a lot of time and effort to become generally deployable in all EU member states, being its main limitation.

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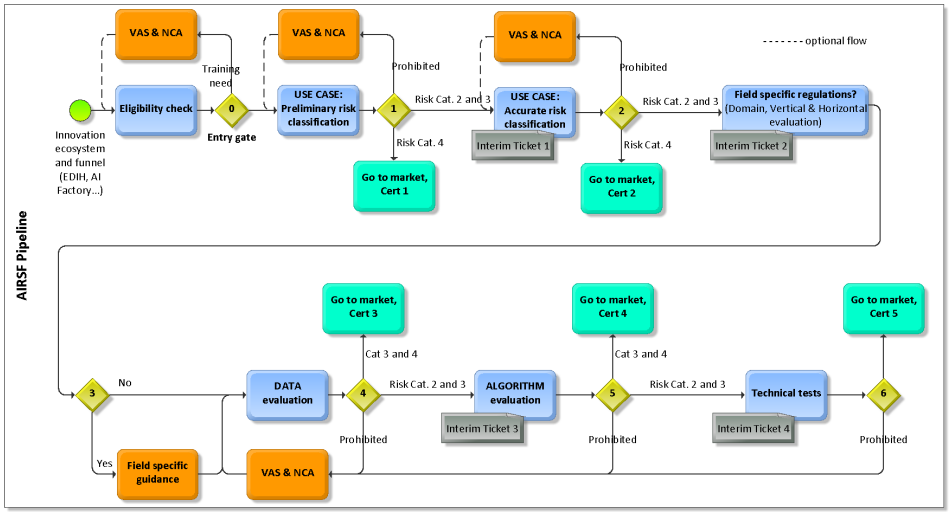
Appendix 1: Categories of AI Systems' use cases

Based on this, we categorise AI systems into the following types:

- **Embedded Single-Purpose AI System**: These involve a single AI model evaluated against a specific business purpose. For example, an AI tool that analyses item quantities. The evaluation within the AI sandbox is straightforward due to the clear boundaries of the use case.
- **Single-Target AI Systems with Multiple Functions**: These AI systems use several AI models to fulfil a specific business need. An example is a traffic monitoring solution that identifies traffic volume (AI model 1) and predicts future traffic based on historical data (AI model 2). The AI sandbox must analyse the compliance of both models as a single AI system against the overarching purpose.
- **General AI Solutions with Single Function**: These systems are more complex due to the open-ended potential of the use case. For example, an object identification system for video analytics may serve functions as diverse as identifying car brands or individuals. The lack of a specific focus complicates the creation of relevant test data and the compliance analysis of an AI System.
- **General AI Solutions with Multiple Functions**: This category includes general-purpose AI (GPAI) systems like ChatGPT, which involve multiple layers of AI models and systems. For the scope of this paper, we exclude GPAI due to the some practical (e.g. the decisive role of AI Office) and fundamental issues around ambiguity of the AIA in relation to GPAI regulation (Lanamäki et al., 2024; Papagiannidis et al., 2025).

Appendix 2: Tentative Stage-Gate –process



Key:

- Innovation ecosystem and funnel (EDIHs, TEFs, AI Factories...) entry to eligibility check
- NCA = National Competent Authority (also Supervisory Authority)
- VAS = Value Added Service (e.g. Innovation Ecosystem (accredited) experts in AI, business, AI and related regulation.
- #0...#6 Stage Gates
- Prohibited = Risk Cat #1
- Risk Cat #2...#4 AI Act risky practices categories
- Cert #1 ... Cert #5 Registering of high-risk AI Systems to EU-database, granting certificates for Risk Cat #2 and #3.
- Interim Ticket #1...#4 For indicating the status of the AI System progress in the process, for performance assessment of the sandbox throughput and signal providers, financiers and potential deployers. Also useful, when switching from sandbox to another.