SPECIFIX
EMPOWERING SURGICAL PRECISION

Ethical AI Capacity Recommendations

Relevant Resources and Advice

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Ethical AI organization

Purpose of this document

Introduction

SPECIFIX is a health tech start-up focused on empowering surgeons with advanced pre-operative planning tools. We are collaborating with them on a project that utilizes AI-driven segmentation to identify and separate bone fragments from CT scans, enabling precise virtual fracture reduction and alignment. By integrating reinforcement learning and 3D segmentation, the solution supports surgeons in planning complex procedures with greater accuracy.

The objective of this document is to assess SPECIFIX's ethical AI organizational capacity, identify potential issues, and provide actionable recommendations for improvement.

Assessment of Current Organization

Listed below are some key advantages that position SPECIFIX to develop excellent ethical-AI driven solutions as well as some opportunities for improvement:

Key Advantages

1. **Expertise Across Disciplines:**

   The SPECIFIX team is composed of highly qualified professionals with exceptional expertise in their respective fields:

   - **Prof. Dr. Matthias Vanhees, MD, PhD –** A professor and hand-and-wrist surgeon with extensive international experience, active research contributions, and a strong academic presence.

   - **Aleejandra Ortega, PhD** – An accomplished leader with a strong foundation in biomedical sciences, specializing in medical imaging and clinical applications.

   - **Soha Mahdi, PhD** – A skilled expert in artificial intelligence, with a vast experience of applying her knowledge to the medical field and guiding research projects.

This diverse team, in which all the members have experience in the medical field fosters a collaborative environment. Furthermore, Soha Mahdi's knowledge on both areas allows to bridge the gap between AI expertise and the necessary medical field domain knowledge for this specific project - anatomy of the wrist and forearm bones and their potential fractures.

2. **Model Transparency and Explainability**

- The **reinforcement learning** approach for virtual fracture reduction is notably transparent, as surgeons can directly observe the inference process through an interactive environment rendering. This allows them to validate and most importantly evaluate the model's outputs effectively in case of any error.

- While bone fracture **segmentation** lacks the same inherent visibility, the training process, can be extensively explained by Soha Mahdi, ensuring that it is understandable for stakeholders and surgeons alike. Furthermore, there is potential to integrate explainable AI (XAI) methods in the future (such as LIME or Grad-CAM) to enhance trust further.

Opportunities for Improvement

1. **Data Ethics:**

SPECIFIX faces challenges in managing class imbalances within its current bone fracture segmentation dataset. This issue arises naturally, as some types of fractures are more prevalent than others. However, the imbalance can affect model performance and fairness. While the **Data Quality Report** provides a detailed overview of the current state, obtaining additional data is essential to strengthen the model's robustness and accuracy

2. **Compliance and Regulations:**

Although partnerships with Vision Lab and a hospital (which will remain nameless for data privacy concerns) demonstrate a commitment to responsible data use, SPECIFIX currently lacks a comprehensive ethical framework. Having an ethical framework is foster trust in AI solutions and ensure responsible use of data. Therefore, a GDPR compliance checklist has been provided to assist SPECIFIX in meeting these regulatory requirements. We have made the checklist as comprehensive as possible; however, completing it will still require significant time and effort on SPECIFIX's behalf.

To address this challenge, we propose supplementary suggestions, tailored recommendations, and resources designed to simplify compliance with the more complex aspects of the General Data Protection Regulation (GDPR). These have been organized by GDPR sections and can be found in the following pages of this document.

3. Company Policy Framework:

SPECIFIX currently lacks a formal company policy framework tailored to ethical AI development and data governance. Establishing a clear, structured policy is crucial for ensuring consistency in decision-making, ethical standards, and demonstrating a commitment to responsible AI practices to stakeholders, partners and data subjects. A well-defined policy helps in setting clear guidelines, managing risks proactively, and fostering trust internally and externally.

To address this gap, we will provide, to the best of our ability, recommendations in this document on how SPECIFIX can implement an effective company policy framework, covering essential components and best practices to align with industry standards and specific regulatory requirements in Belgium.

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GDPR - Lawful Basis and Transparency

Resources and reccomendations

Legal Justification for data processing activities

According to [Article 6(1)(a)](#) of the General Data Protection Regulation (GDPR), SPECIFIX has a lawful basis to process personal data as they have obtained the explicit consent of the data subjects. The article states, "Processing shall be lawful only if and to the extent that at least one of the following applies: (a) the data subject has given consent to the processing of his or her personal data for one or more specific purposes." SPECIFIX ensures that all data subjects are fully informed about the purposes of data processing and provide clear, unambiguous consent, thereby adhering to this legal requirement.

GDPR - Data Security

Resources and reccomendations

Create an internal security policy for your team members and build awareness about data protection.

For GDPR Training we suggest Measured Collective's GDPR training course. It is an introductory course so no previous knowledge is required, it is free, and Measured Collective specializes in data protection training for regulations such as GDPR and PECR.

Have a process in place to notify the authorities and your data subjects in the event of a data breach.

GDPR requires organizations to have a Breach Notification Plan in case data breaches ever occur. We have found a template that already includes Communication Templates. We recommend appointing the Belgian Data Protection Authority (GBA/APD) as your Supervisory Authority Contact and using the provided Communication templates.

GDPR - Privacy Rights

Resources and reccomendations

Request Forms

For the Privacy Rights component of the GDPR checklist, multiple request forms are required to address various data subject rights. We identified two resources that could assist in creating these forms:

1. Advisera's GDPR Consent & Data Subject Rights Toolkit
2. Formstack's Data Subject Rights Request Form template

While these resources are paid, their free versions provide foundational elements that could serve as the basis for developing SPECIFIX's data request forms.

Company Policy Framework

Resources and relevant information

How is a company policy created?

The first step for creating a company policy will be to outline the necessary steps. Indeed, a globally recognized employment website that aggregates job listings, performs company reviews and provides Career Development resources for employees and companies alike has created an article in which they outline the [steps to writing meaningful company policies and procedures](#)

Here is a summary of the points referenced in the article:

1. Identify your goals: Define the objectives your policies and procedures aim to achieve, ensuring they address organizational needs like efficiency, morale, or profitability.
2. Brainstorm tasks and processes: Analyze current operations to identify areas where new or revised policies can make the greatest impact.
3. Decide on your format: Choose a clear and consistent format for presenting policies to ensure readability and compliance with industry standards.
4. Write policies and procedures: Draft detailed rules and guidelines, consulting best practices and stakeholders for input and compliance.
5. Consider the impact of your changes: Evaluate the potential effects of policy changes on workflows, ensuring they meet goals with minimal disruption.
6. Proofread and revise: Edit for clarity, correctness, and precision, ensuring no ambiguity before obtaining approvals.
7. Publish and distribute: Share finalized policies with employees through appropriate channels, such as handbooks, emails, or direct communication.

It's important to note that SPECIFIX already possesses a clear vision of their goals and are already preparing to implement the GDPR checklist we prepared for them. However, it's important to find resources suited for a start-up in Belgium which operates on the medical field.

Resources for legal structures in Belgium

Although Belgium is part of the European Union, and frameworks like GDPR are common across European countries, Belgium - like any other country - has its own specific legal requirements and regulations.

We would like to highlight that law is **not our area of study, nor are we offering legal advice**. However, we would like to provide a **reliable resource** to find specific legal structures and documents necessary for company policies - the [Business Belgium website](#).

Business Belgium is a government-operated platform designed to assist entrepreneurs and businesses with practical information about setting up and managing a company in Belgium. The website provides detailed guidance on various legal structures, registration processes, tax requirements, and compliance documentation. We believe this will be a useful and trustworthy resource because, once again, it is a **government-operated platform.**

Resources for organizations in the Health sector

Another important aspect to consider when creating a company policy is that SPECIFIX operates in the health sector. Navigating the health industry requires not only understanding general business regulations but also addressing specific standards, innovation opportunities, and compliance requirements unique to this field.

We recommend [BioWin](#) as a valuable resource in this context. BioWin is the Health Cluster of Wallonia, Belgium, and serves as a regional hub for innovation in health biotechnology and medical technologies. It connects companies, research centers, and universities, fostering collaboration and supporting research and development projects.

For SPECIFIX, BioWin offers an opportunity to access expert knowledge, networking opportunities, and guidance tailored to the health sector. This resource can help align your company policies with best practices and compliance within the industry.

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