Enhancing Digital Health Systems Through the Novel Digital Clinical Safety Platform

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Abstract: The Digital Clinical Safety Platform (DCSP) represents a significant advancement in streamlining and automating clinical safety documentation for digital health systems. Built in alignment with established clinical safety standards including DCB0129 and DCB0160, the DCSP offers a user-friendly interface and integrates innovative methodologies, including git-based version control, hazard typing, and the novel DevSecRegOps framework. These features enable seamless documentation of hazards, mitigations, and compliance directly within the development pipeline, fostering "safety by design."

The platform combines dynamic and static documentation capabilities. Its adaptable templates support diverse safety standards while ensuring consistency and reusability across projects. By bridging the gap between developers, clinical safety officers, and regulatory stakeholders, the DCSP enhances collaboration and delivers an audit trail that improves accountability and transparency. Early trialling by an established clinical safety consultancy firm has shown the DCSP's potential to reduce manual workflows, minimise errors, and foster continuous improvement in clinical risk management. Furthermore, as an open-source platform, the DCSP encourages community-driven enhancements, offering transparency, flexibility, and cost efficiency for its users.

This paper explores the design, functionality, and future roadmap of the DCSP, including its potential for integration into organisational safety processes and its capacity to transform the management of digital health systems on a global scale. A demonstration of the DCSP can be viewed at https://youtube.com/live/xzLJkN9NLeU.

Introduction: Digital health systems are increasingly complex, requiring robust frameworks to ensure patient safety and regulatory compliance. Traditional methods of clinical safety documentation, often reliant on static tools such as spreadsheets and word processors, fail to meet the dynamic needs of modern healthcare systems. The Digital Clinical Safety Platform (DCSP) addresses these limitations by leveraging advancements in software engineering and clinical safety standards to deliver a comprehensive, user-centric solution for managing digital health safety documentation.

Core Features of the DCSP: The DCSP integrates several key features designed to enhance the efficiency and reliability of clinical safety workflows:

1. **Git-Based Version Control:** By utilising git, the platform ensures that all changes to safety documentation are traceable, fostering accountability and enabling detailed audit trails. Version control allows users to track the evolution of safety mitigations and assess the impact of software updates on existing hazards.

2. **Hazard Typing and Logging:** The platform introduces novel structured hazard typing, aligning with international safety standards. This feature categorises hazards into predefined types, streamlining risk identification and mitigation processes while reducing redundancy across projects.
3. **DevSecRegOps Framework:** Building on the principles of DevOps, the DCSP incorporates security and regulatory compliance directly into the product lifecycle. The DevSecRegOps framework incorporates development, security, regulation and operations from product inception and then continuously for the duration of the project. This framework integrates clinical safety requirements with continuous integration and deployment workflows, ensuring real-time alignment between software development and regulatory standards.
4. **Dynamic and Static Documentation:** The DCSP provides both interactive and static documentation formats. Users can dynamically update placeholders and templates, tailoring safety documentation to specific project needs, while also generating static PDFs for regulatory submissions.
5. **Open-Source Transparency:** As an open-source platform, the DCSP promotes collaboration and innovation within the healthcare community. By allowing stakeholders to review, customise, and contribute to the codebase, the platform fosters transparency, accelerates development cycles, and reduces implementation costs.

Impact and Early Adoption: The DCSP has been trialling by an established clinical safety consultancy firm, receiving positive feedback for its intuitive interface and transformative potential. Clinicians and developers have highlighted the platform's ability to reduce manual workflows, standardise safety documentation, and facilitate collaboration across multidisciplinary teams. Additionally, the platform's support for reusable templates has the potential to significant time savings and improved accuracy in clinical safety cases.

Future Directions: While the DCSP is currently in the prototype phase, it requires minimal input to be production ready. Future iterations aim to include advanced features such as:

- Graphical process mapping for enhanced visualisation of hazards and mitigations.
- Conditional logic to support complex safety workflows.
- Trend analysis tools for monitoring risk profiles across multiple projects.
- Integration with quality management systems to unify safety and operational objectives.
- Regional and national hazard logging of digital systems, akin to the "Yellow Card" system used in the UK for drug side effects. This would lead to shared learning of hazards and overall increased system safety across the region/nationally.

Conclusion: The DCSP represents a paradigm shift in managing clinical safety for digital health systems. By embedding safety practices directly into the software development lifecycle and leveraging modern engineering tools, the platform enhances collaboration, reduces errors and hazards, and ensures regulatory compliance. Its early trialling and positive feedback underscores its potential to become a global standard for digital clinical safety management. Ongoing development and community engagement will further refine the DCSP, ensuring it continues to meet the evolving needs of healthcare organisations worldwide.

Keywords: Clinical safety, digital health, hazard logging, DevSecRegOps, patient safety, healthcare technology, regulatory compliance.