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Abstract Title: Software for Practical Annotation and Exchange of Virtual Anatomy (**æva**): Design Considerations

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Abstract Text: Representation of anatomy in a virtual form is at the foundation of biomedical research – including but not limited to biomedical simulations, and clinical practice. Virtual anatomies – of the whole body, organs, tissues, cells, are important digital assets with significant reuse potential. Contemporary high throughput analysis also requires effortless acquisition, generation, modification, and exchange of these digital assets. A unified software, however, to deal with anatomy in a highly fragmented ecosystem of scientific and clinical applications, is missing. The goal of this abstract is to present our proposed solution, **æva**, a free and open source software for practical annotation and exchange of virtual anatomy. Specifically, broad design considerations for the software are summarized. Anatomy is represented in various forms in a digital environment: as medical images, as CAD based geometry, as mesh-based representations (surface or volume) all depending on the context of its use. For example, a radiologist may use an image-based representation for diagnostics, an engineer may rely on CAD based formats for implant design, and those who are interested in individualized prototyping, e.g., for additive manufacturing, and physics-based simulations will utilize meshes. All such use cases also necessitate a large variety of annotation capabilities that can be generalized to mark anatomical regions, to describe anatomical properties and relations, and to assign physical properties and states. **æva** aims to support different forms of anatomical representation (and related annotation operations) and commonly used image, geometry, and mesh formats. This capacity will provide an exchange pathway within a representation approach. Nonetheless, it is important to note that **æva** also aims to provide capabilities to move between different anatomical representations, e.g., image to geometry or mesh, mesh to image, so on, including transfer of annotation across data types, longitudinal study entries, or cohort members. An extensible data structure will support unification of anatomical information from different sources, and potentially in different formats. Low and high level APIs, will provide the basis for biomedical computational pipelines, which in future can support unsupervised, high-throughput analyses and cloud based services. A GUI will support interactive engagement. Free and open source software development philosophy will promote the broad use of **æva**, permitting academic or commercial use by any interested party. We anticipate that **æva** will provide significant utility for management, standardization, curation, and exchange of anatomical data and metadata (including common data elements). In return, it will facilitate physics-based modeling and large scale analysis, e.g., big data analytics, machine learning, which increasingly depend on the harmonization of multiscale anatomical and physiological data. In regard to latter, **æva** can be used to generate labeled virtual anatomy ground truth data for training machine learning models. The aforementioned design considerations of **æva** are also in response to broad dissemination, provenance, and conformance to standards guidance from reproducibility and credibility frameworks in modeling and simulation.