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Same and different: Version 4 of the eCTD standard

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The electronic common technical document standard, established in 2003, has been a boon for both regulators and drug sponsors, as it speeds review and provides a consistent framework for market, and investigational trial authorization. It has been implemented in the US, the European Union, Switzerland, South Africa, the Gulf Coast Consortium, and is accepted in many other countries as the primary electronic review medium. Version 4 of the standard is a radical change to the packaging of the authorization dossiers—but with no change to the actual content. Its benefits include greater flexibility to support more submission and product types, but will require updates to software. With FDA about to accept version 4 in a pilot program, it is critical to learn how this will affect your company. This session will explore the technical issues that will make implementation difficult, but also the similarities that make regulatory's job nearly unchanged.

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