The VICTRE Trial: Open-Source, In-Silico Clinical Trial For Evaluating Digital Breast Tomosynthesis

Summary

Expensive and lengthy clinical trials delay regulatory evaluation of innovative medical technologies affecting patient access to high-quality medical products. Sophisticated simulation tools are increasingly being used in device development, but are rarely used in regulatory applications. We investigate a new paradigm for evaluating digital breast tomosynthesis (DBT) as a replacement for digital mammography (DM), using exclusively in-silico methods.

A total of 2986 subjects, with breast sizes and radiographic densities representative of a screening population and compressed thicknesses from 3.5 to 6 cm, were simulated and imaged on in-silico versions of DM and DBT systems using fast Monte Carlo x-ray transport. Images were interpreted by a computational reader detecting the presence of lesions. The in-silico trial (VICTRE) was designed to replicate a comparative trial from a previous regulatory submission. The endpoint was the difference in area under the receiver-operating-characteristic curve between modalities (delta-AUC) for lesion detection. Using a fully-crossed design, VICTRE was sized for a standard error (SE) of 0.01 in delta-AUC, half the uncertainty seen in the comparative trial. A 1-hour summary presentation of the project and findings was given at the FDA Grand Rounds on 3/14/2019 and can be found here.

A systematic exploration of the trial parameters including lesion types and sizes is also possible and greatly facilitated by the availability of open-source, free software tools available at https://github.com/DIDSR/VICTRE.

Data Access

Data Access

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Detailed Description

Detailed Description

Collection Statistics	Updated
Modalities	MG
Number of Participants	2994
Number of Studies	8749

Number of Series	8749
Number of Images	217913
Image Size (TB)	1.03

Citations & Data Usage Policy

Citations & Data Usage Policy

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Dataset Citation

Badano A, Graff CG, Badal A, Sharma D, Zeng R, Samuelson FW, Glick S, Myers KJ. **The VICTRE Trial: Open-Source, In-Silico Clinical Trial for Evaluating Digital Breast Tomosynthesis**. 2018. DOI: 10.7937/TCIA.2019.ho23nxaw .

Publication Citation

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TCIA Citation

Clark K, Vendt B, Smith K, Freymann J, Kirby J, Koppel P, Moore S, Phillips S, Maffitt D, Pringle M, Tarbox L, Prior F. **The Cancer Imaging Archive (TCIA): Maintaining and Operating a Public Information Repository**, Journal of Digital Imaging, Volume 26, Number 6, December, 2013, pp 1045-1057. DOI: 10.1007/s10278-013-9622-7.

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Versions

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