

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

Click the **Download** button to save a ".tcia" manifest file to your computer, which you must open with the [NBIA Data Retriever](#). Click the **Search** button to open our Data Portal, where you can browse the data collection and/or download a subset of its contents.

Data Type	Download all or Query/Filter
Images (DICOM, 1.03 TB)	 
Software (Github)	

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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

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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](https://doi.org/10.7937/TCIA.2019.ho23nxaw) .

Publication Citation

Badano A, Graff CG, Badal A, Sharma D, Zeng R, Samuelson FW, Glick SJ, Myers KJ. **Evaluation of Digital Breast Tomosynthesis as Replacement of Full-Field Digital Mammography Using an In Silico Imaging Trial**. JAMA Netw Open. 2018;1(7):e185474. DOI: [10.1001/jamanetworkopen.2018.5474](https://doi.org/10.1001/jamanetworkopen.2018.5474).

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](https://doi.org/10.1007/s10278-013-9622-7).

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Versions

Version 1 (Current): Updated 03/08/2019

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