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

Reproduced from https://wiki.cancerimagingarchive.net

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

Data Type	Download all or Query/Filter	License
Images (DICOM, 1.03 TB)	*Download Search* (Download requires the NBIA Data Retriever)	CC BY 3.0

Additional Resources for this Dataset

The NCI Cancer Research Data Commons (CRDC) provides access to additional data and a cloud-based data science infrastructure that connects data sets with analytics tools to allow users to share, integrate, analyze, and visualize cancer research data.

- Imaging Data Commons (IDC) (Imaging Data)

The following external resources have been made available by the data submitters. These are not hosted or supported by TCIA, but may be useful to the researchers utilizing this collection:

- Software (Github)

Detailed Description

Detailed Description

	Radiology Imaging Statistics
Modalities	MG
Number of Participants	2,994
Number of Studies	8,749
Number of Series	8,749

Reproduced from https://wiki.cancerimagingarchive.net

Number of Images	217,913
Image Size (TB)	1.03

Citations & Data Usage Policy

Citations & Data Usage Policy

Users must abide by the TCIA Data Usage Policy and Restrictions. Attribution should include references to the following citations:

Data 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

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.

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.

Other Publications Using This Data

TCIA maintains a list of publications which leverage our data. If you have a publication you'd like to add please contact the TCIA Helpdesk .

Versions

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

Data Type	Download all or Query/Filter
Images (DICOM, 1.03 TB)	*Download* *Search* (Download requires the NBIA Data Retriever)

Reproduced from https://wiki.cancerimagingarchive.net