Total Gallium

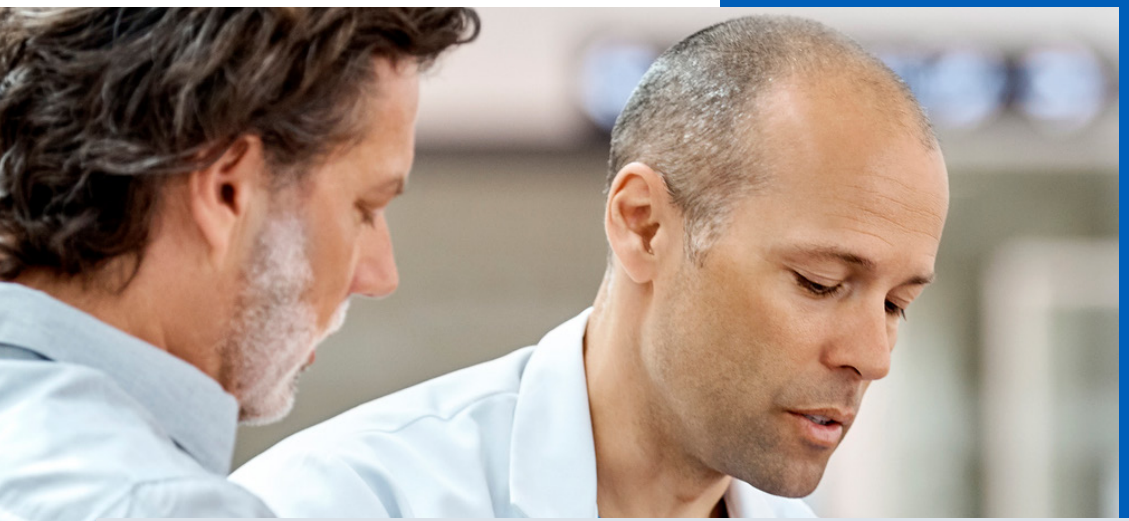
On-demand.

gehealthcare.com

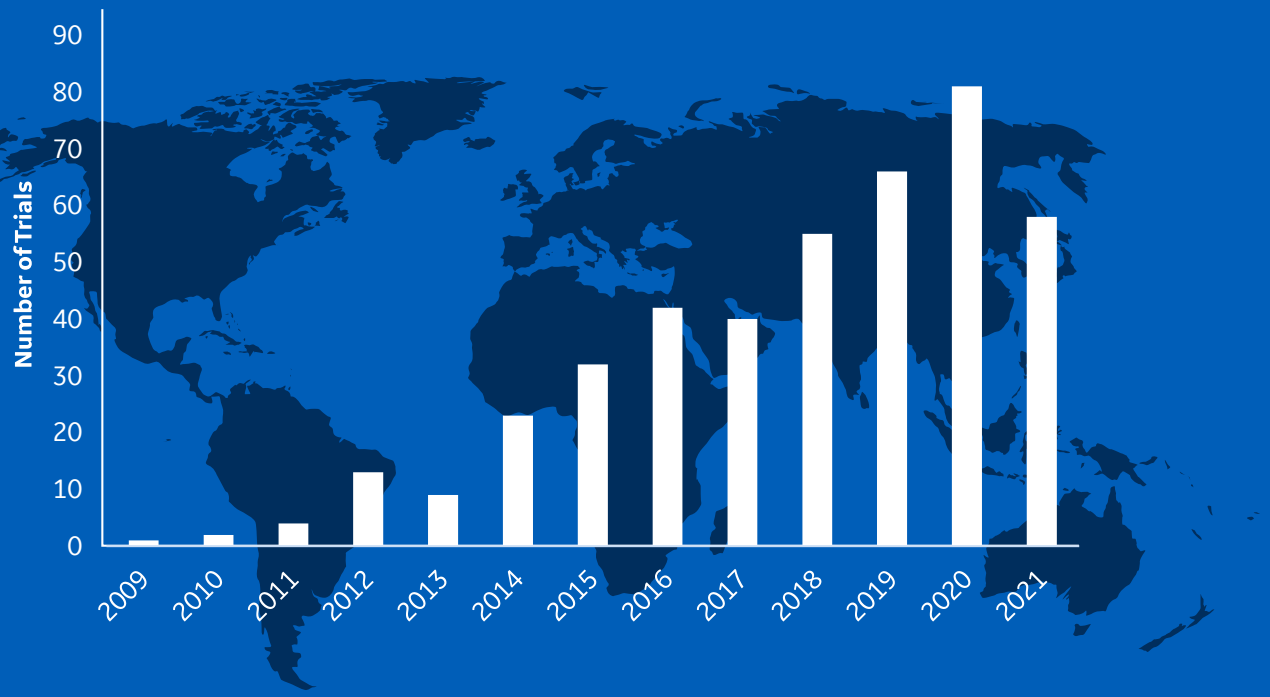
Total Gallium is GE's cyclotron-produced ^{68}Ga supply solution

A cost-effective, predictable alternative to generator-supplied Gallium 68 for prostate cancer research and clinical therapy.

GE has been an active member of the Molecular Imaging community, driving progress together with our users for a technological innovation to enable an alternative source of ^{68}Ga tracers.



The rapid rise in published clinical studies using ^{68}Ga is driven by the development of ^{68}Ga tracers for imaging of neuroendocrine tumor (NET) and prostate cancer (PCa), now the most common cancer in men.



Number of ^{68}Ga clinical trials starting per year*

*clinicaltrials.gov (July 29, 2021) – search terms: 68Ga/Ga68/68Gallium/Gallium68

Clinical trials using ^{68}Ga is expanding in numbers and across the globe.

^{68}Ga clinical trials distribution*

*clinicaltrials.gov (July 29, 2021) – search terms: 68Ga/Ga68/68Gallium/Gallium68

Generators Cannot Meet the Growing Clinical Demand

There's a long wait time.

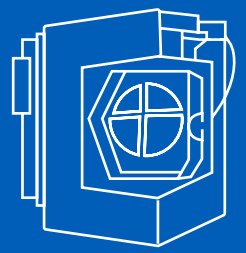
~ 12 months for a new generator or replacement generator.

They are expensive.

~ $80K each for a market authorized generator, replaced approximately every 6 months.

Patient scheduling issues.

Decay of the ^{68}Ge results in an increase in cost per elution and decrease in the number of possible doses over time.



Cyclotron Gallium Chloride

VS

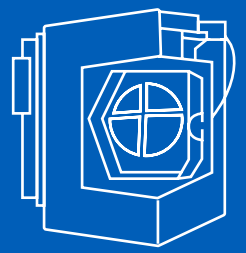
Generator Gallium Chloride

2X

If a cyclotron was run or a generator was eluted once a day, for a year:

A cyclotron can produce at least two times* the amount of gallium chloride compared to a generator.

*Based on a PETtrace cyclotron liquid target versus a new 50 mCi generator



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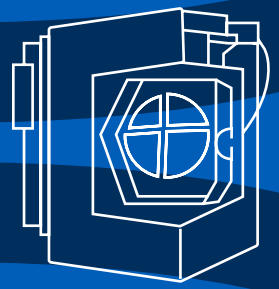
Added benefits of cyclotron production:

- Produce ^{68}Ga on-demand
- The supply of ^{68}Ga is not depleting due to parent ^{68}Ge decay as is in the case of a generator

*Based on a PETtrace cyclotron liquid target versus a new 50 mCi generator



PETtrace 800 cyclotron
PETtrace ^{68}Ga Liquid Target

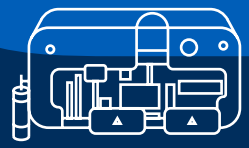
FASTlab Platform
FASTlab $GaCl_3$ cassette

Further labeling
or kit labeling

Quality control

Dispensing

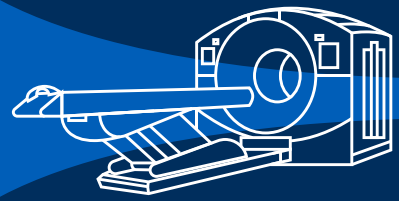
Total Gallium is an integrated suite of technologies and support that ensures a consistent, reliable, and cost-effective supply of ^{68}Ga tracers to meet your clinical and research needs.



FASTlab Platform
FASTlab Developer Cassette

Quality control

Dispensing



Discovery MI PET/CT

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FASTlab $GaCl_3$ cassette

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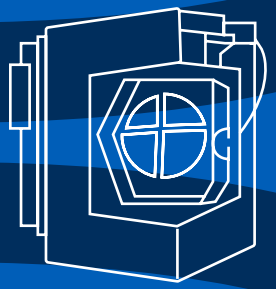
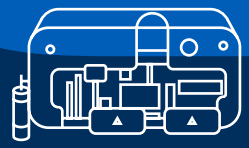


PETtrace 800 cyclotron
PETtrace ^{68}Ga Liquid Target

GE delivers subject matter expertise in the implementation of **Total Gallium** technologies and provides regulatory support to smoothly enable your compliant and clinical production of cyclotron ^{68}Ga tracers.



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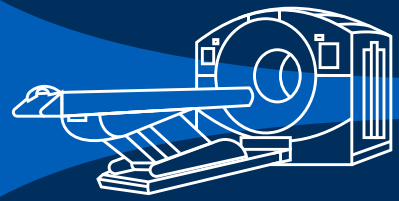
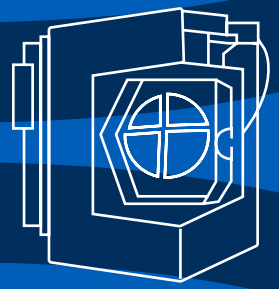


Discovery MI PET/CT

The PETtrace™ cyclotron and ^{68}Ga liquid target system delivers isotope on demand.



PETtrace 800 cyclotron
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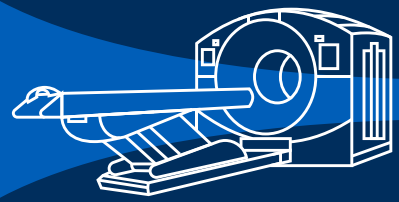

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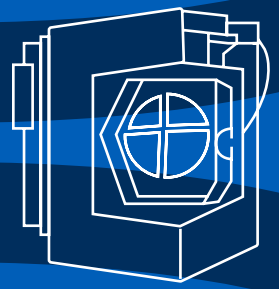


PETtrace 800 cyclotron
PETtrace ^{68}Ga Liquid Target

Purify cyclotron-produced ^{68}Ga for further research endeavors or kit labeling* with the FASTlab™ platform and the FASTlab Gallium Chloride Cassette.

FASTlab Platform
FASTlab $GaCl_3$ cassette

Further labeling or kit labeling

Quality control

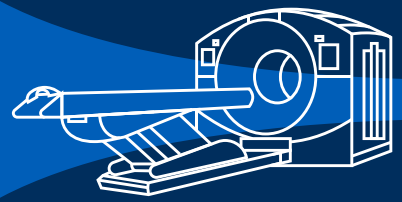
Dispensing

GE delivers subject matter expertise in the implementation of **Total Gallium** technologies and provides regulatory support to smoothly enable your compliant and clinical production of cyclotron ^{68}Ga tracers.

FASTlab Platform
FASTlab Developer Cassette

Quality control

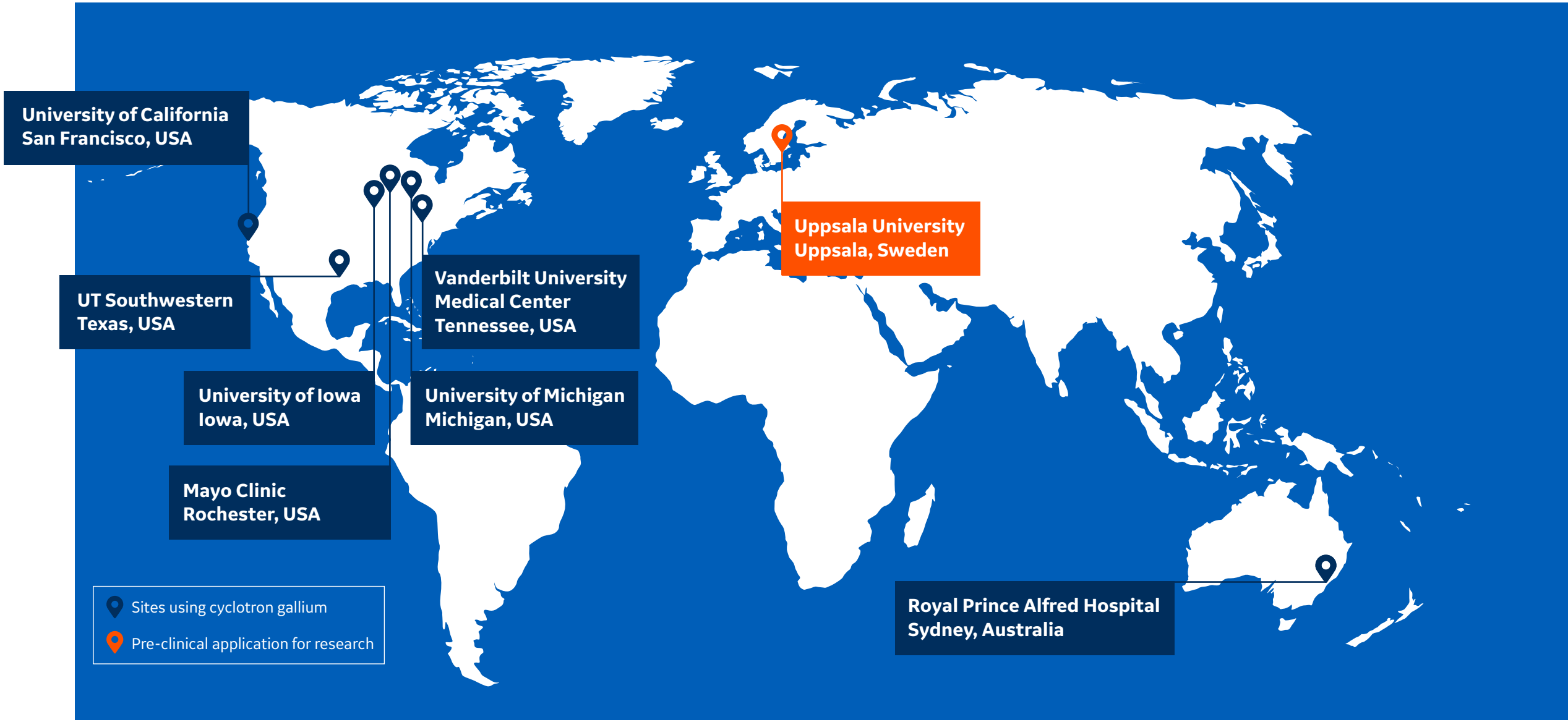
Dispensing



Discovery MI PET/CT

Purify and label in one step various ^{68}Ga tracers with the FASTlab platform and FASTlab cassettes for clinical applications. Support is available for [^{68}Ga]Ga-PSMA-11 and DOTA-based ^{68}Ga-tracer labeling.

*On-going efforts with kit manufacturers



Cyclotron-produced gallium clinical efforts around the world

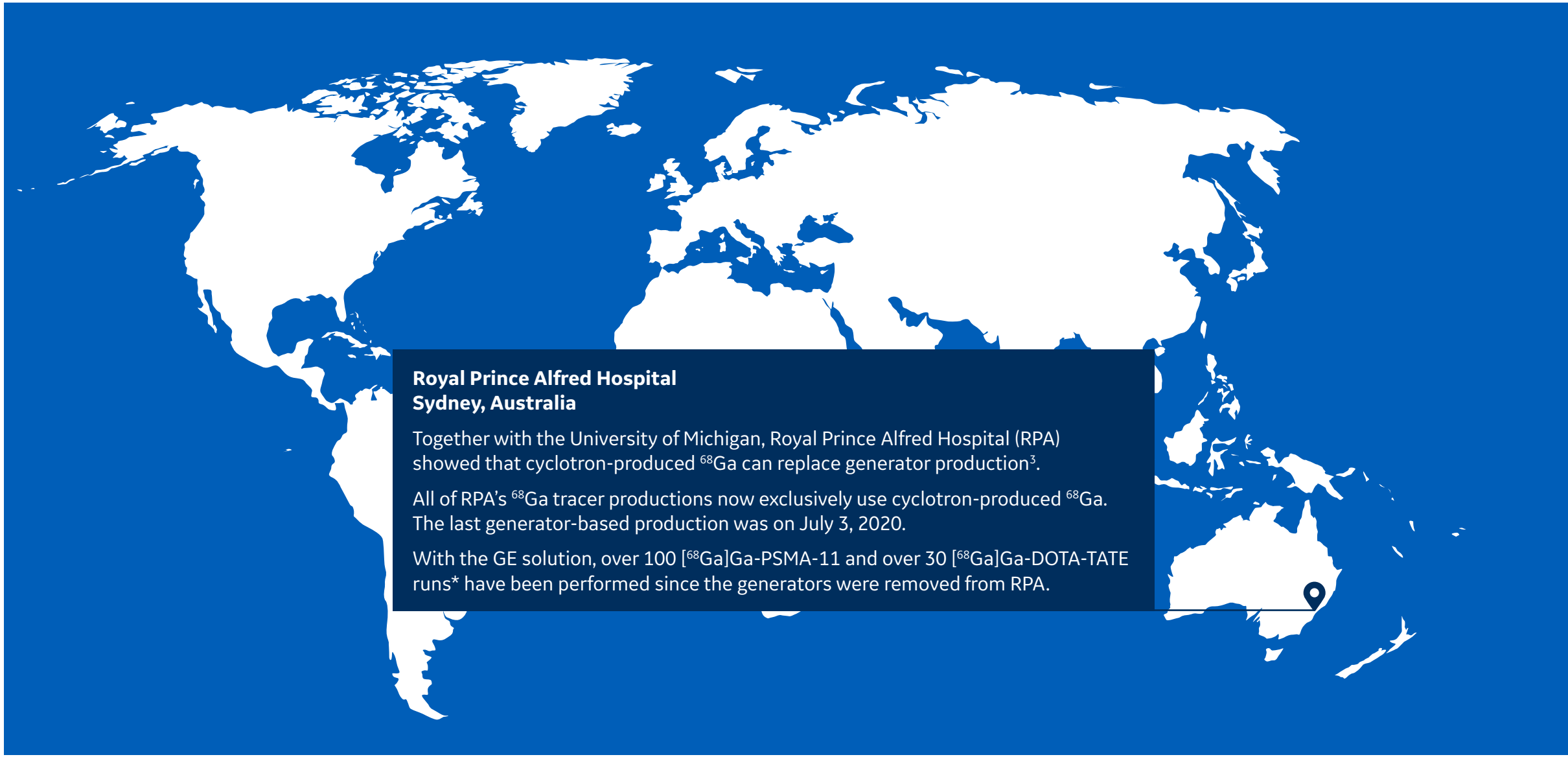
University of Michigan
Michigan, USA

More than 1000 [^{68}Ga]Ga-PSMA-11 scans have been performed since 2016 with continued growth. The generators cannot continue to meet the University of Michigan's (UM) growing demand for ^{68}Ga-tracers.

With two PETtrace cyclotrons and three ^{68}Ga liquid target systems, UM has scanned more than 100 patients with cyclotron-produced [^{68}Ga]Ga-PSMA-11 since February 2019.

To meet the projected 3000 ^{68}Ga scans per year, Dr. Peter Scott's group has recently produced nearly 100 mCi of [^{68}Ga]Ga-PSMA-11 in one run using dual bombardment methods[2].

[2]Gagnon et. al. Cyclotron-based ^{68}Ga production with dual liquid targets. Eur J Nucl Med Mol Imaging (2020) 47 (Suppl 1): S1–S753, OP-954



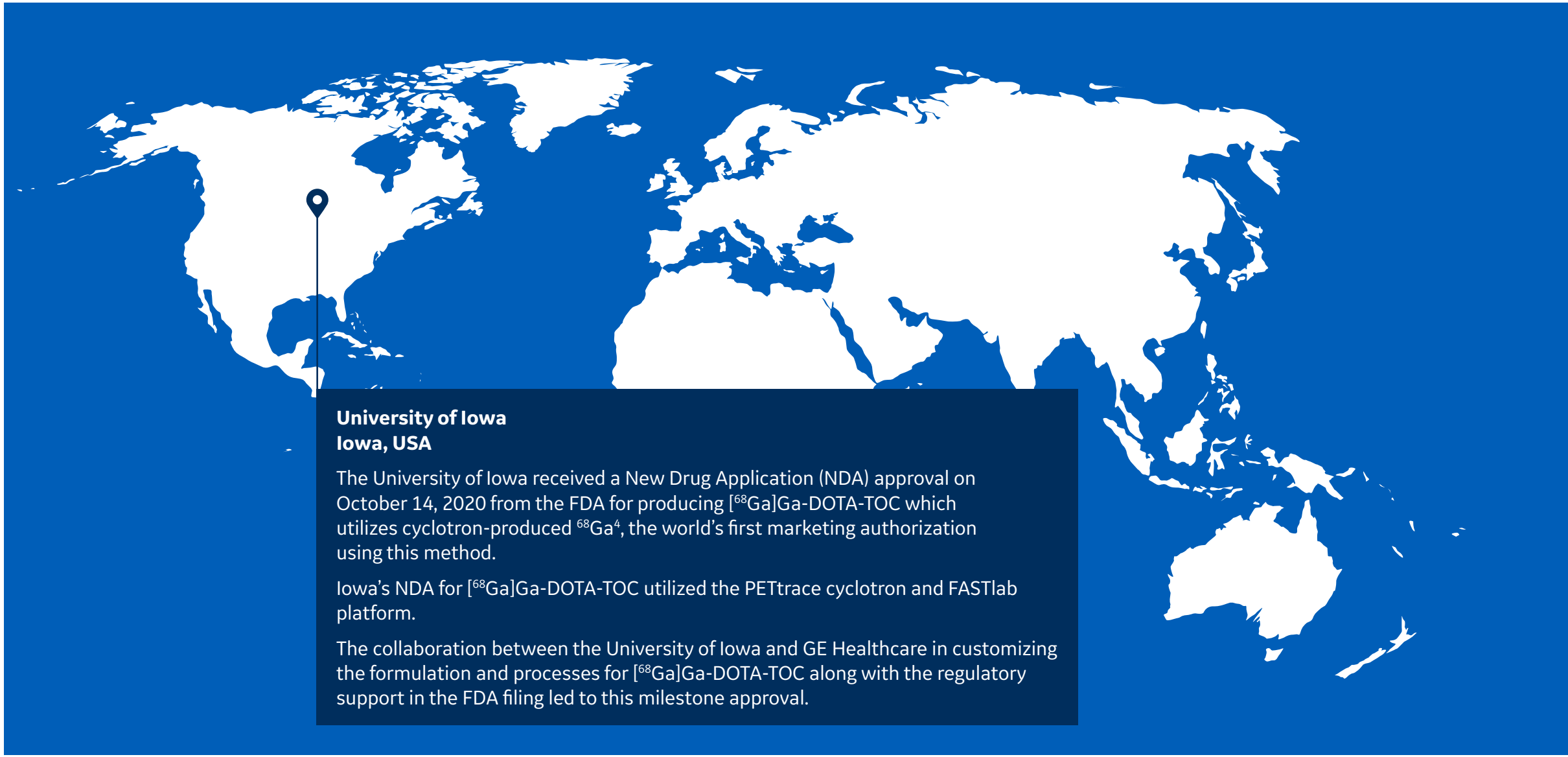
Royal Prince Alfred Hospital
Sydney, Australia

Together with the University of Michigan, Royal Prince Alfred Hospital (RPA) showed that cyclotron-produced ^{68}Ga can replace generator production[3].

All of RPA's ^{68}Ga tracer productions now exclusively use cyclotron-produced ^{68}Ga. The last generator-based production was on July 3, 2020.

With the GE solution, over 100 [^{68}Ga]Ga-PSMA-11 and over 30 [^{68}Ga]Ga-DOTA-TATE runs* have been performed since the generators were removed from RPA.

[3] Rodnick, M.E., Sollert, C., Stark, D. et al. Cyclotron-based production of ^{68}Ga, [^{68}Ga]GaCl[3], and [^{68}Ga]Ga-PSMA-11 from a liquid target. EJNMMI radiopharm. chem. 5, 25 (2020).
* As of January 2021. The average +/-SD (max) activity at EOS: [^{68}Ga]Ga-PSMA-11: 1783 +/- 238 MBq (2280 MBq), [^{68}Ga]Ga-DOTA-TATE: 1683+/-284 MBq (2130 MBq). [^{68}Ga]Ga-PSMA-11 and [^{68}Ga]Ga-DOTA-TATE are currently not regulatory approved in Australia, RPA is producing under exemption of the Therapeutic Goods Act (TGA) in a TGA GMP-licensed facility.



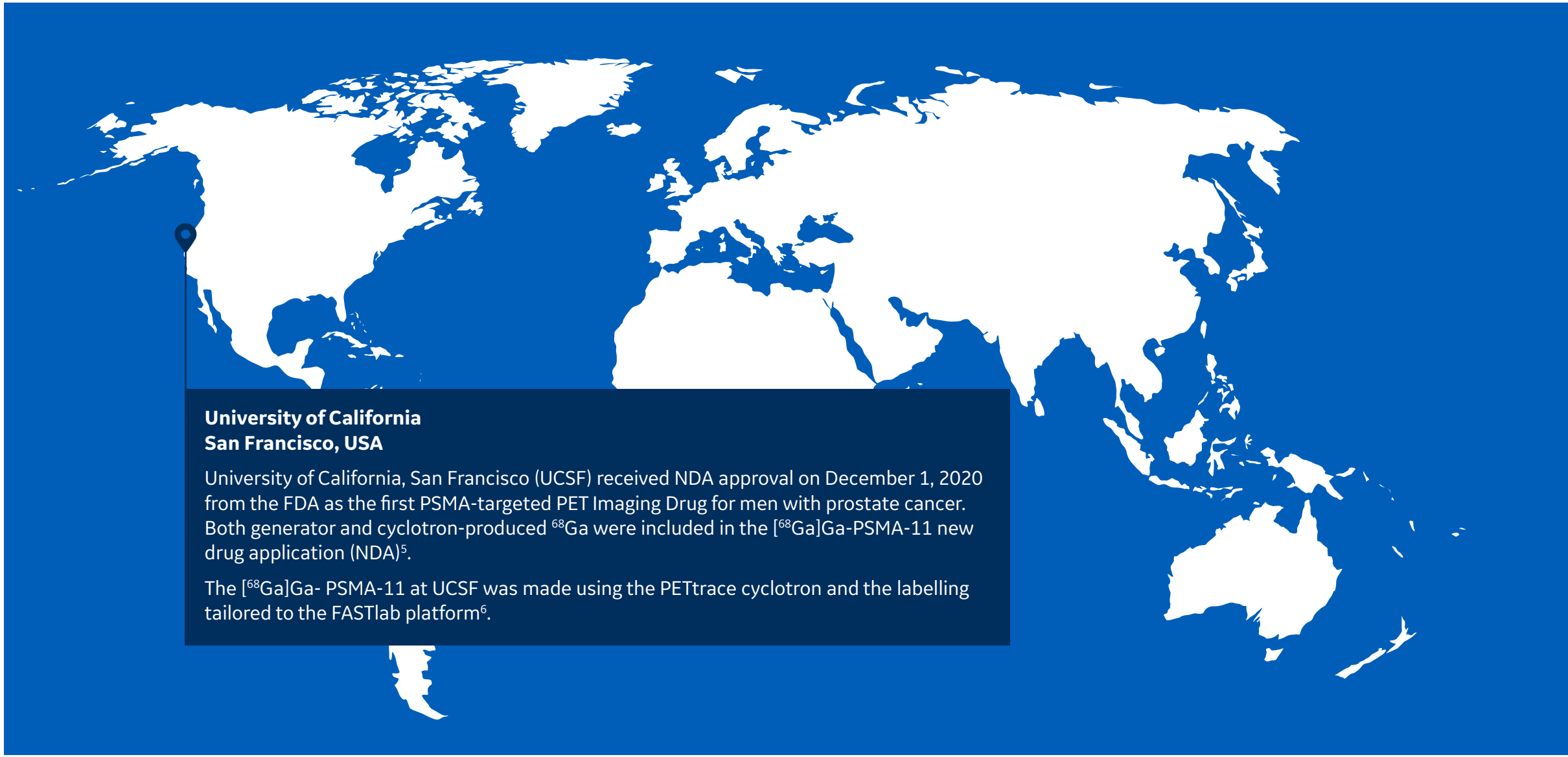
University of Iowa
Iowa, USA

The University of Iowa received a New Drug Application (NDA) approval on October 14, 2020 from the FDA for producing [^{68}Ga]Ga-DOTA-TOC which utilizes cyclotron-produced ^{68}Ga[4], the world's first marketing authorization using this method.

Iowa's NDA for [^{68}Ga]Ga-DOTA-TOC utilized the PETtrace cyclotron and FASTlab platform.

The collaboration between the University of Iowa and GE Healthcare in customizing the formulation and processes for [^{68}Ga]Ga-DOTA-TOC along with the regulatory support in the FDA filing led to this milestone approval.

[4] SNMMI Press Release: FDA Approves Cyclotron-Produced Ga-68 DOTATOC for Neuroendocrine Tumors
http://www.snmmi.org/NewsPublications/NewsDetail.aspx?ItemNumber=34801



University of California
San Francisco, USA

University of California, San Francisco (UCSF) received NDA approval on December 1, 2020 from the FDA as the first PSMA-targeted PET Imaging Drug for men with prostate cancer. Both generator and cyclotron-produced ^{68}Ga were included in the [^{68}Ga]Ga-PSMA-11 new drug application (NDA)[5].

The [^{68}Ga]Ga- PSMA-11 at UCSF was made using the PETtrace cyclotron and the labelling tailored to the FASTlab platform[6].

[5] FDA approves First PSMA-Targeted PET Imaging Drug for Men with Prostate Cancer
https://www.fda.gov/news-events/press-announcements/fda-approves-first-psma-targeted-pet-imaging-drug-men-prostate-cancer

[6] Carlucci et al. 68Ga-PSMA-11 NDA Approval: A Novel and Successful Academic Partnership, Journal of Nuclear Medicine Dec 2020, jnumed.120.260455
https://jnm.snmjournals.org/content/early/2020/12/18/jnumed.120.260455

[7] Rinne, S.S., Abouzayed, A., Gagnon, K. et al. ^{66}Ga-PET-imaging of GRPR-expression in prostate cancer: production and characterization of [^{66}Ga]Ga-NOTA-PEG2-RM26. Sci Rep 11, 3631 (2021).

Building a world that works

About GE Healthcare:

GE Healthcare is the $18 billion healthcare business of GE (NYSE: GE). As a leading global medical technology and digital solutions innovator, GE Healthcare enables clinicians to make faster, more informed decisions through intelligent devices, data analytics, applications and services, supported by its Edison intelligence platform. With over 100 years of healthcare industry experience and around 50,000 employees globally, the company operates at the center of an ecosystem working toward precision health, digitizing healthcare, helping drive productivity and improve outcomes for patients, providers, health systems and researchers around the world.

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Note: Radiopharmaceuticals may not be approved by ministers of health in all regions. Customers should ensure approval by local country regulatory authorities.

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