

Centre for Probe Development and Commercialization (CPDC)

Bruno Paquin

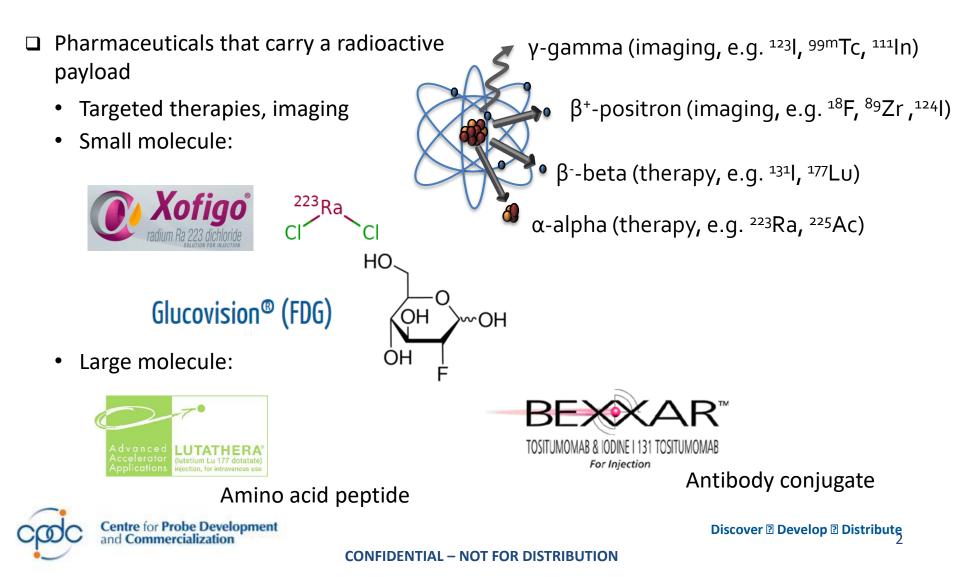
May 27th, 2019



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Radiopharmaceuticals



CPDC Overview

- CPDC is a "not-for-profit" corporation that was founded in 2008 to:
 - ✓ Provide a reliable supply of radiopharmaceuticals.
 - Advance discovery and development of innovative nuclear medicine products.
 - ✓ Create commercial entities to advance new products.
- Health Canada approved facilities (Hamilton & Ottawa) and products (e.g. FDG and NaF).



- HQ: Hamilton, Ontario (McMaster University Campus).
- □ Three cyclotrons and multiple cleanrooms in manufacturing network.
- Leading developer/supplier of research and commercial PET products in Ontario.
- □ Supported by federal and provincial grants, and product revenues.



Mission

Be <u>the</u> "go-to" Centre of Excellence for development, translation and commercialization of diagnostic AND therapeutic radiopharmaceuticals

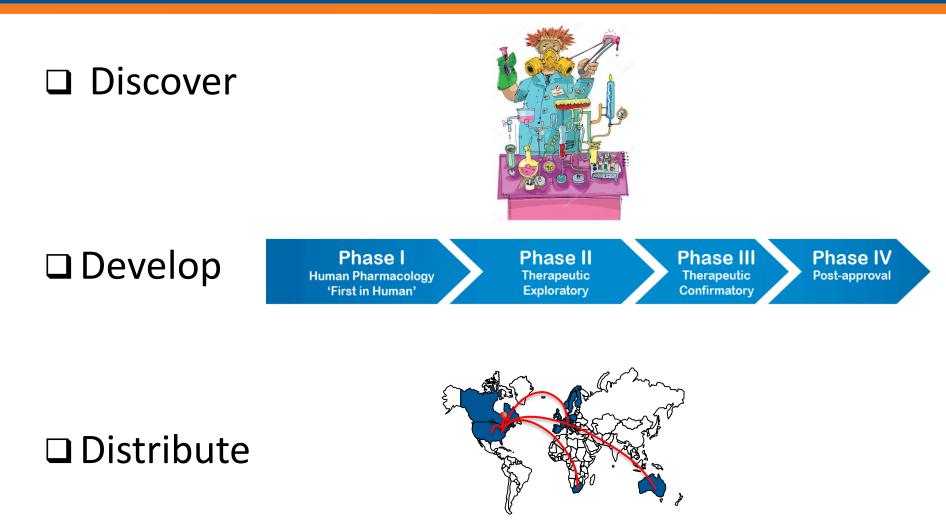
Create and maintain a self-sustaining ecosystem to support Canadian research in nuclear medicine

Bring new products to Canada through academic and industry partnerships

Enable better outcomes for Canadian patients by providing high quality products for the diagnosis and treatment of disease

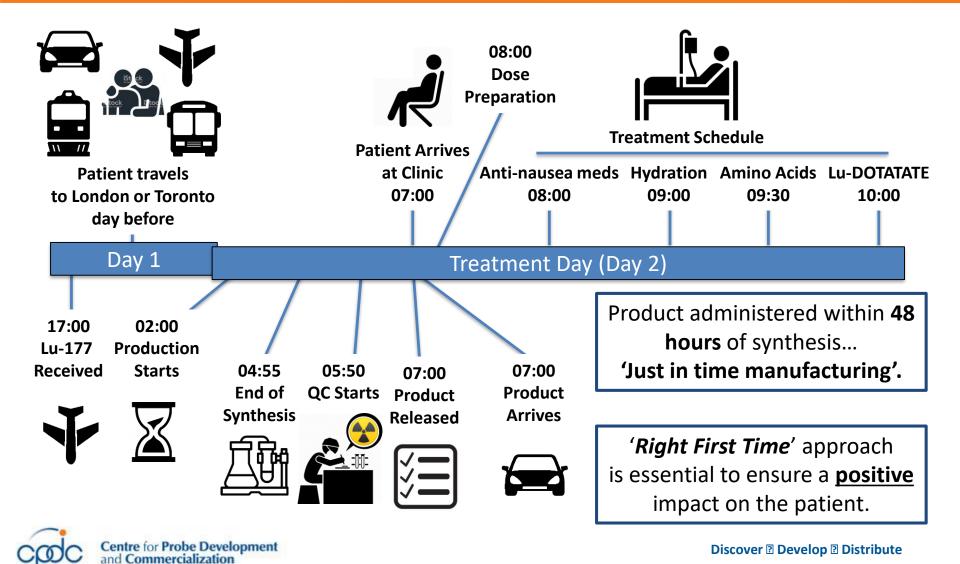


Strength





A day in the life of a patient



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Strong Network of Partners

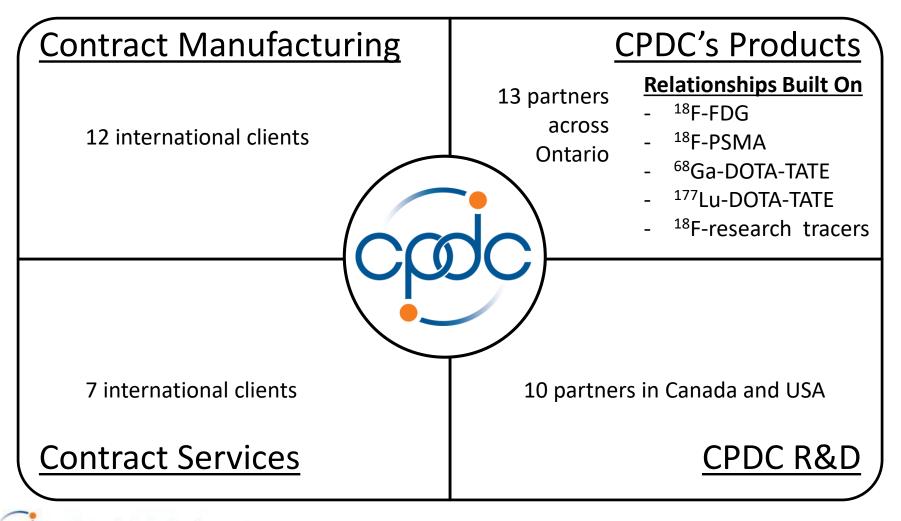
- Foundational partner McMaster University supports CPDC's manufacturing facilities and offices on McMaster's campus.
- Long standing clinical relationship with
 University Health Network through joint venture with CPDC (CanProbe)
- University of Ottawa Heart Institute is a international leader in cardiac imaging working with CPDC on FDG supply that is expanding into clinical stage products
- Immuno-oncology program being initiated in Boston with the Dana Farber Cancer Institute





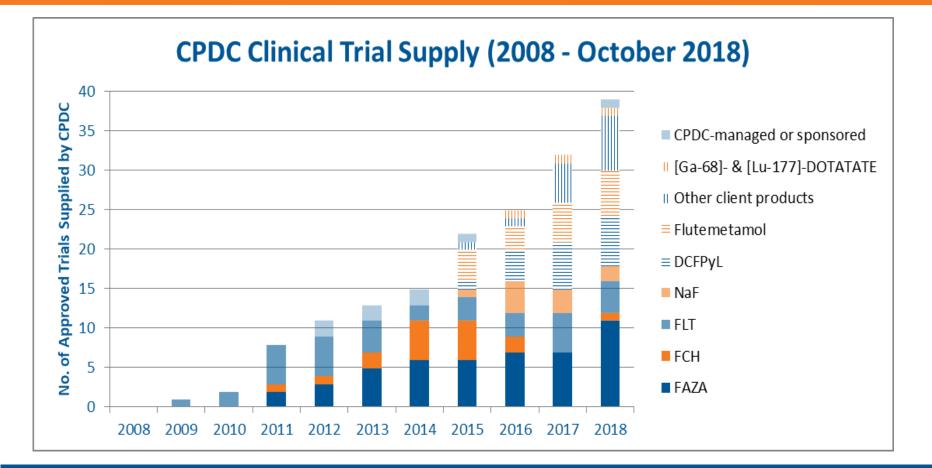


Clients and Stakeholders



Centre for Probe Development and Commercialization

Supporting Clinical Research in Ontario



Use of CPDC products in clinical research has increased year over year!



Important Programs

Neuroendocrine Imaging and Therapy

- CanProbe, supported by CPDC manufacturing and regulatory programs, establish supply programs for ⁶⁸Ga and ¹⁷⁷Lu-DOTATATE
- CPDC will seek regulatory approval for these products
- Prostate Cancer Imaging and Therapy
 - CPDC, with the help of collaborators and major funding agencies, has taken a major leadership role in changing how Prostate Cancer is diagnosed and treated in Canada
 - ¹⁸F-DCFPyL program spearheaded by CPDC/CanProbe (funded by Movember)
 - Next generation ¹⁸F-PSMA (PSMA-1007) program in development to allow enhanced imaging of prostate bed
 - CPDC owns the licence for PSMA-1007. This is a novel metastatic prostate cancer imaging agent developed by ABX advanced biochemical compounds GmbH
 - ¹⁷⁷Lu-PSMA therapy program ramping up to support Prostate Cancer Canada initiative





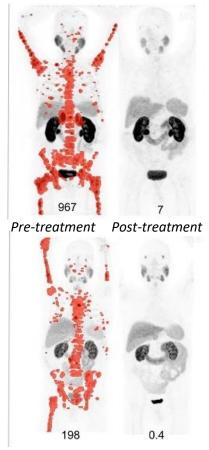




Prostate Cancer Canada Supported Treatment Trial

- Canadian therapy clinical trial with Lu-177 PSMA-617 (supported by Endocyte)
 - CPDC is providing CMC and Regulatory expertise and will be a supplier of the Lu-177 based therapy
 - BCCA will lead the clinical program
- CPDC's program is <u>on schedule</u> to supply a 300 patient trial
- Expected trial start in Fall 2019

SNMMI Image of the Year



J Nucl Med May 1, 2018 vol. 59 no. supplement 1 531



CPDC Outreach – Company Creation



Lead CPDC's R&D team \$46M in 2017 and \$105M in 2019



Joint venture BCCA, TRIUMF, Lawson and CPDC Solid target technology



Joint venture UHN-CPDC R&D and clinical trial support



Contract Manufacturing Organization

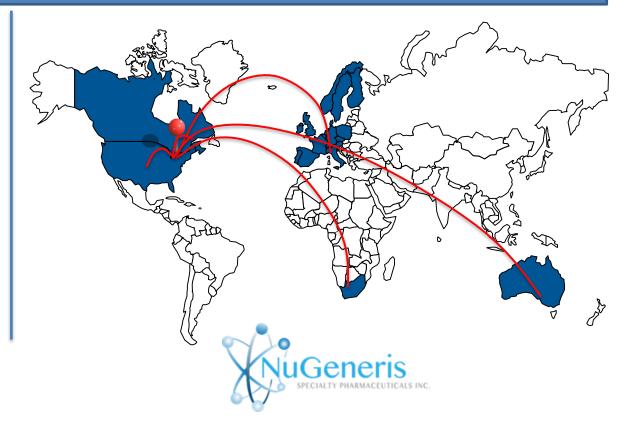
NewCos Two more planned, Specialty pharma, Diagnostic



World Class Manufacturing Program

CPDC is a leading manufacturer and distributor of radiopharmaceuticals
 Combination of branded generics and partner products
 Profitable and rapidly growing business, basis of NuGeneris spin-out

12 International Clients





NuGeneris



• Initiate commissioning in 2021

The Commercial Facility

NUGENERIS'S WILL CONSTRUCT THE 1ST COMMERCIAL, PURPOSE-BUILT, RADIOTHERAPEUTICS MANUFACTURING FACILITY.

Capacity

- 24,000 sqft
- >200 units per day
- 24/7 operation, daily production
- 50,000+ units per year

Infrastructure

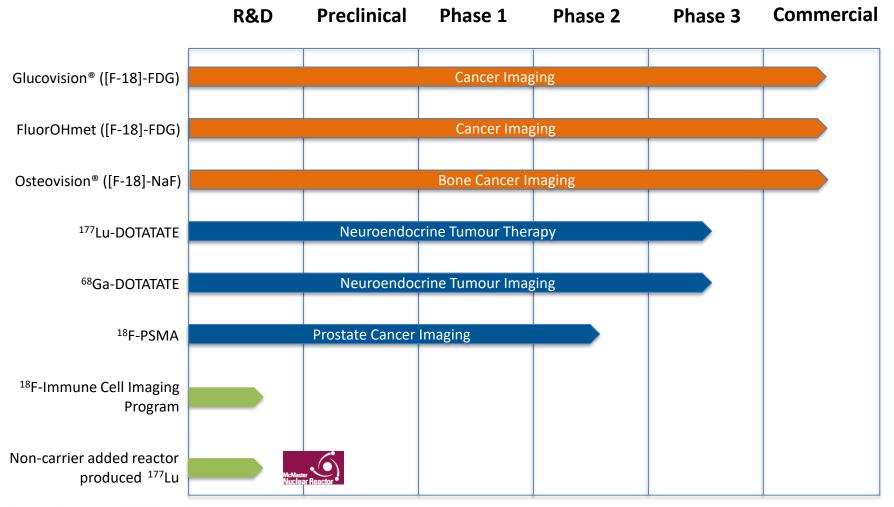
- cGMP cleanrooms
- High-volume production & fill/finish lines
- QC laboratories
- Warehouse & Distribution
- 150 employees at its peak
- Commercial supply in 2024

CA\$ 14M Investment Secured*

*Conditionally



CPDC's Product Pipeline





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