



NorthStar<sup>®</sup>

# Ac-225 Program Overview

Workshop on Standards and Measurements  
for Alpha Emitting Nuclides in Therapeutic  
and Nuclear Medicine



Daniel J. De Vries, Ph.D.

Senior Director, Medical Radioisotope Product Development

# Advanced Radiopharmaceutical and Therapeutic Technologies

NorthStar's Mission: Providing Patients Global Access to Game-Changing Radiopharmaceuticals

## Experienced Leadership

- Highly experienced leadership team with decades of proven success
- Fully supported by NorthStar's Board and Senior Leadership
- Dedicated resources
- Multiple Supply Agreement in place with others expected in the rest of 2024



## Extensive Infrastructure

- 100% owned manufacturing infrastructure
- Designed for global supply and distribution
- Proven foundation in producing cGMP radioisotopes - >2M+ patient doses served
- Multiple FDA approvals and inspections



## Electron Beam Technology

- Third IBA TT-300 HE Rhototron installed
- Intense focus on
  - > Strategic Partnerships
  - > Facilities design & construction
  - > Waste management
  - > Radon mitigation
- Facilities designed with **reliability, redundancy, flexibility & scalability** as a priority



## Secure Source Material and Long-lead Items

- Long lead items secured and propriety technology in progress to support large scale commercial manufacturing
- Multiple sources and sufficient quantities of starting material to meet future production needs



# Industry Leadership

## Asset Overview

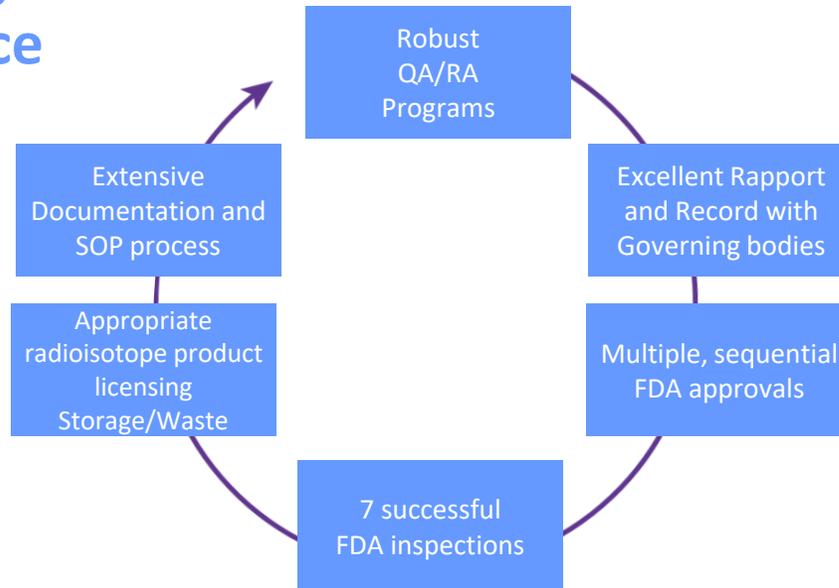
One of a kind facility and equipment specific to the Industry

HPGe, ICP-MS, MP-AES, LaBr3, LSC, radio-HPLC, IC, Hot Cells, Glove Boxes, Isolators, RadLabs, MicroLabs

Radioisotope Technical Expertise  
SME's

3 Ph.D. Physicists / Nuclear Engineers  
8 Ph.D. Radiochemists  
6 Nuclear Pharmacists  
Dozens of Engineers and support staff

## Governing Compliance



## Awards and Industry Recognition

- 1 Frost & Sullivan 2020 Visionary Innovation Leadership Award
- 2 DOE's Outstanding Achievement Award
- 3 WCI (World Council of Isotopes)  
Recognized for outstanding contributions to isotopes
- 4 ABC of Wisconsin's Projects of Distinction  
Excellence in Construction Gold Award
- 5 R&D Top 100 Award for Innovation
- 6 EPA-Green Challenge Award Nominee
- 7 Packaging Innovation award
- 8 Isotope Processing Facility Award

NorthStar will be the first and only U.S. company housing commercial-scale, multi-radioisotope production and radiopharmaceutical development services on the same campus, enabling collaborator companies to realize logistical, regulatory, and cost benefits

n.c.a. Ac-225 Production facility  
(construction underway)

Accelerator  
Production facility

cGMP-Compliant  
Manufacturing facility

Isotope Processing facility

Corporate HQ



# 55 acre Campus Designed with a Purpose

Living our Mission to Provide Patients Global Access to Game-Changing Radiopharmaceuticals



n.c.a. Ac-225 Production facility  
(construction underway)

Accelerator  
Production facility

cGMP-Compliant  
Manufacturing facility

Isotope Processing facility

Corporate HQ



Aerial View  
showing property  
lines



Additionally, two R&D facilities in Madison, WI (including an R&D RAM License location)

# NorthStar's Actinium Manufacturing Process



## Ra-226 Target

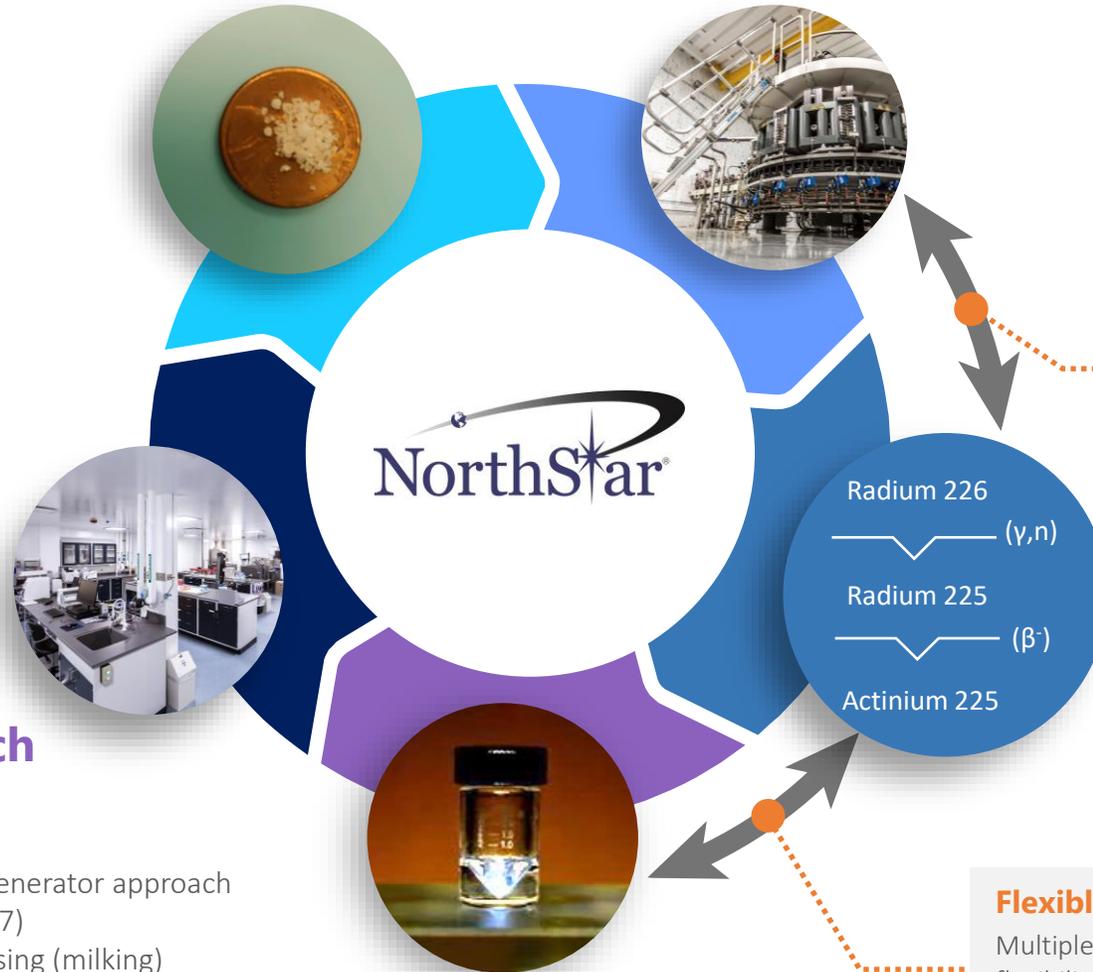
Ra-226 Source Material

## Ra-226 Reprocessing Recover and Reuse

Reclamation is an integral part of NorthStar's process - aids in maintaining costs while reducing the reliance on external suppliers for such a scarce isotope

## Ac-225 Generator Approach n.c.a. Ac-225

NorthStar's Rhototron + process chemistry + generator approach eliminates actinium impurities (Ac-226 / Ac-227)  
Decoupling irradiations from generator processing (milking) provides Ac-225 to customers even during accelerator maintenance periods / outages



## E-Accelerator Irradiation Rhodotron® TT300-HE

NorthStar's High Energy Electron Accelerator (125 kw) has the ability to produce up to 200 Ci/year

### Flexible Ra-225 Production

Optimize Ra-226 usage via adjustable accelerator power, customized target mass, and variable irradiation times to meet changing demand

## Ra-225 Processing Dissolution and Generator Process

Generators contain purified radium solutions which produce n.c.a. Ac-225

### Flexible Ordering

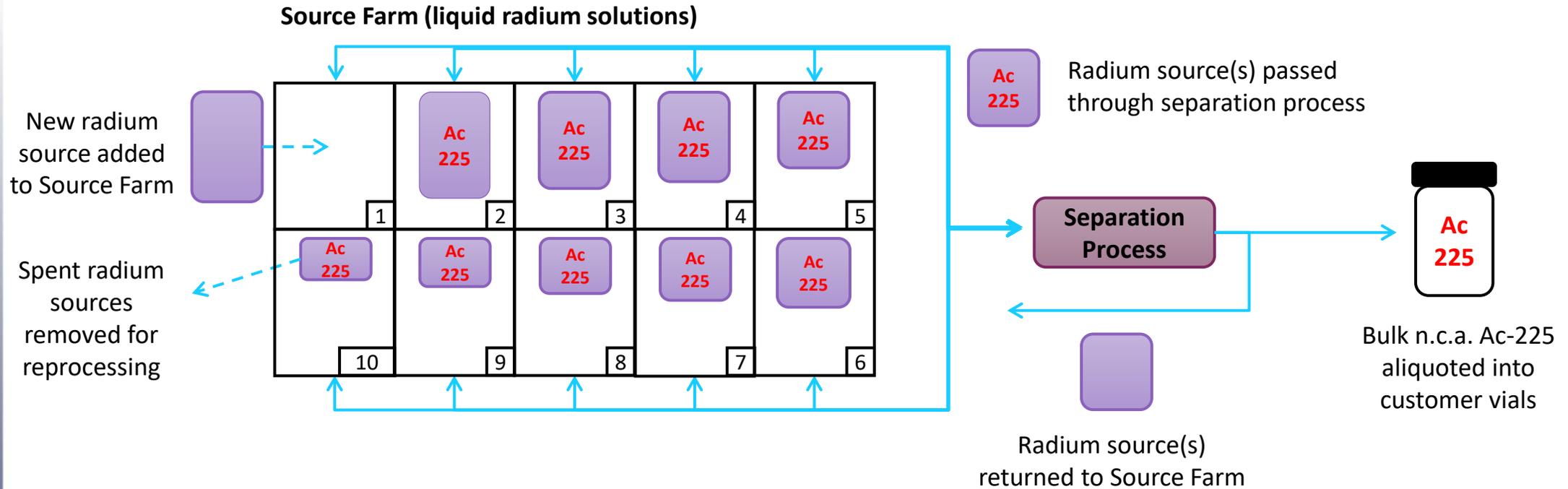
Multiple generators maximize flexibility in meeting customer demand (available 7 days/week)



# Actinium Generator Process

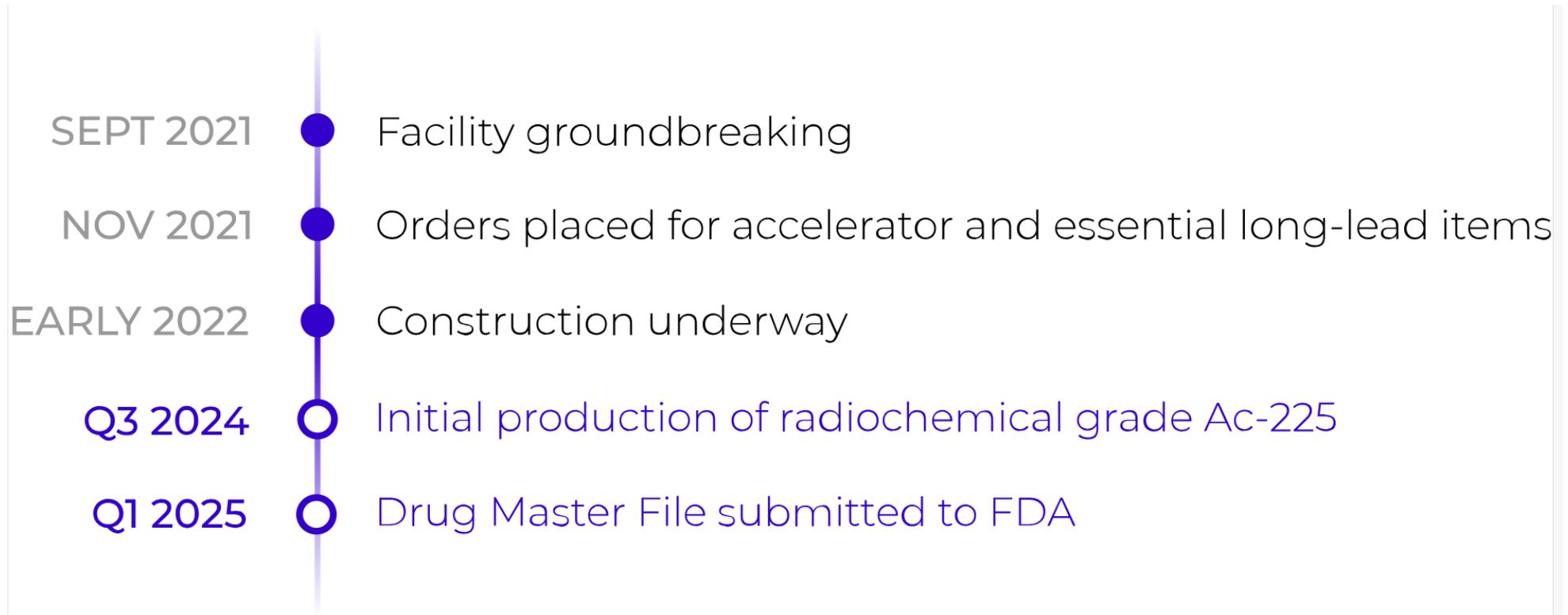
**Radium Sources**

- Aqueous solution of Ra-225
- Ac-225 grows in over time
- New source produced weekly



# High Level Timeline for Ac-225 Production

*We are working to further optimize our time to market*



# Summary

## Ac-225 Manufacturing Cornerstones

- 1 — n.c.a. Ac-225 — NorthStar demonstrates their commitment to provide commercial quantities of Ac-225
- 2 — Dedicated Infrastructure — NorthStar has the technology, experience and resources to provide Ac-225 per our projected timeline
- 3 — Reliability/Redundancy — Proven and ongoing experience with all regulatory agencies
- 4 — Regulatory Expertise — Radiochemical grade Ac-225 potentially available late Q3 2024 – GMP Q1-Q2 2025
- 5 — Flexible Ordering/Logistics

# Please Visit Our Website!

[www.northstarm.com](http://www.northstarm.com)

Follow us on

