Industry and Test Reactors: Collaboration for Production of Medical Isotopes

TRTR & IGORR: Research Reactor Conference
University of Maryland, College Park
June 22, 2023

Sarah Jones, Serva Energy
Chris Bryan, ORNL
Patrick Ruddock, AtomVie

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Serva Energy was founded in 2017 focused on developing accident tolerant fuels (ATFs).

Spring 2022, ASU Mayo Clinic Med Tech Accelerator.

Technology that underpins our fuel innovation – **Smart Nuclear Materials** - used to develop novel reactor-based production methods for rare life-saving isotopes.

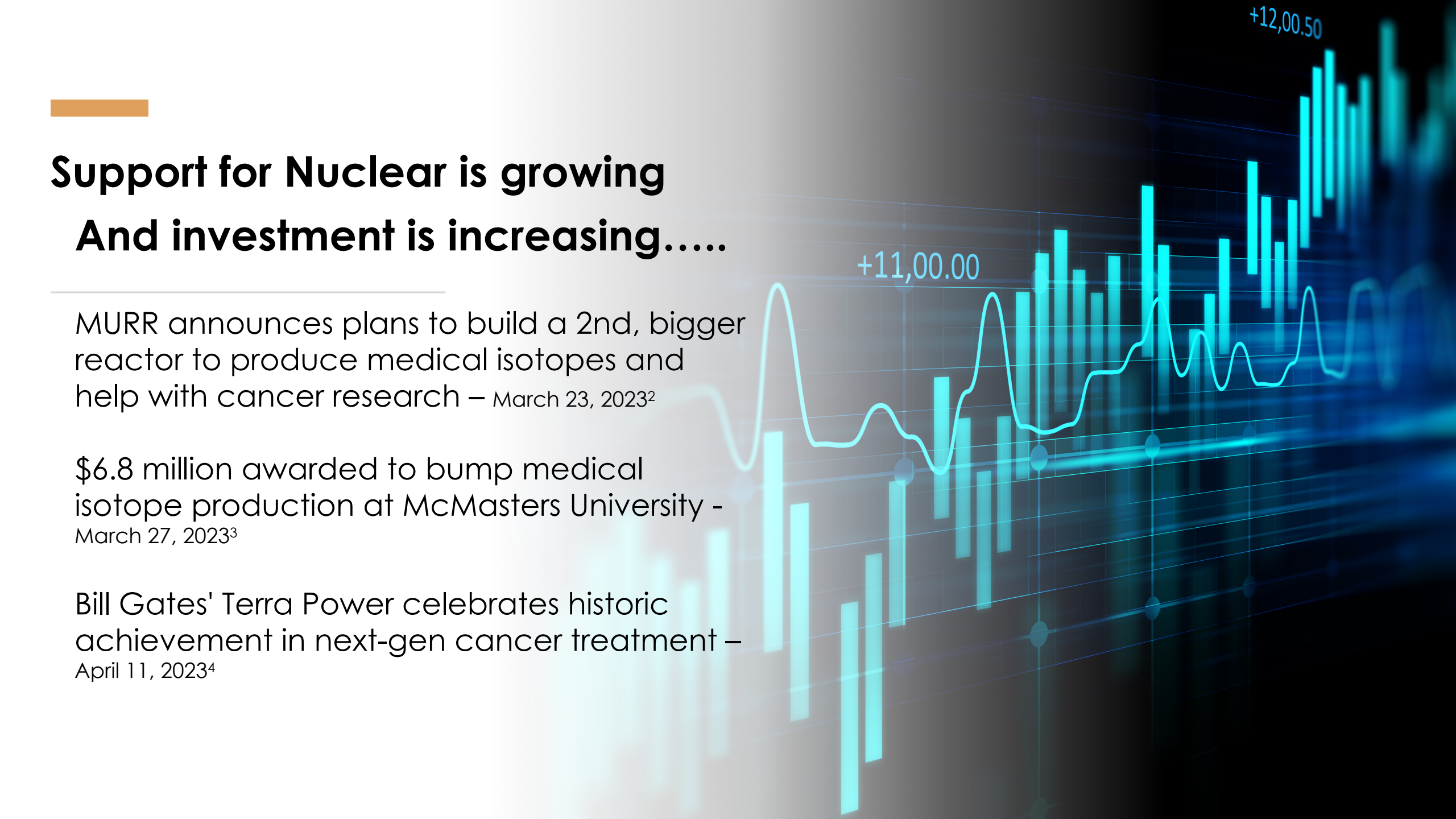
Support for Nuclear is growing

And investment is increasing…..

MURR announces plans to build a 2nd, bigger reactor to produce medical isotopes and help with cancer research – March 23, 2023[2]

$6.8 million awarded to bump medical isotope production at McMasters University - March 27, 2023[3]

Bill Gates' Terra Power celebrates historic achievement in next-gen cancer treatment – April 11, 2023[4]



Production of Medical Radioisotopes at Oak Ridge National Laboratory

Chris Bryan

Industry perspective: Partnering with Research Reactors to Develop Ac-225

Sarah Jones

Medical Isotopes: Regulatory Considerations

Patrick Ruddock

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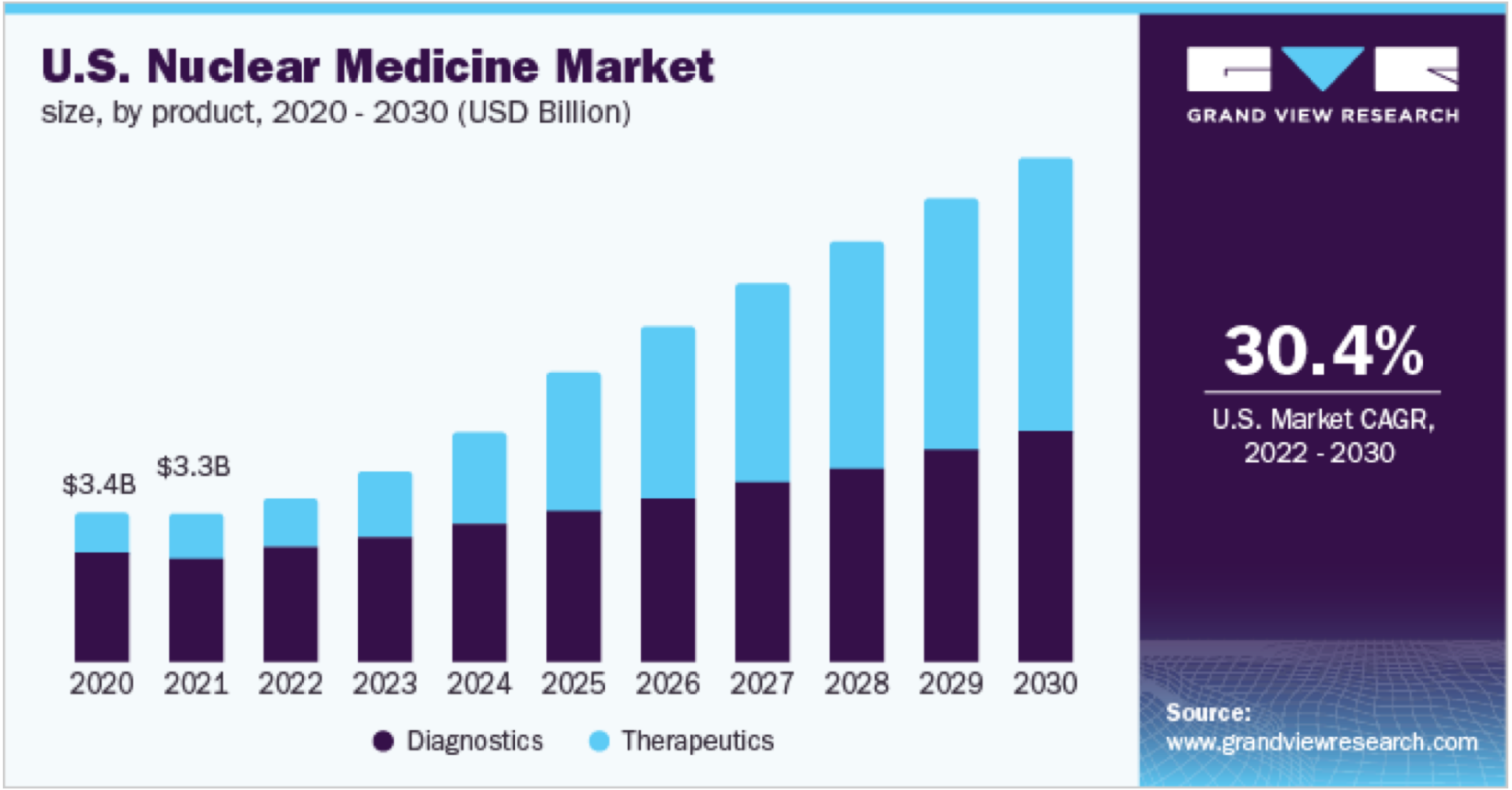
Industry perspective: Partnering with Research Reactors to Develop Ac-225

Sarah Jones, PhD, MGM

Medical Isotope Market

- $8.9 Billion global market
- North America - 45% market share
- Projected 13% compound annual growth rate from 2022-2030 – projected $24.4 Bil by 2030

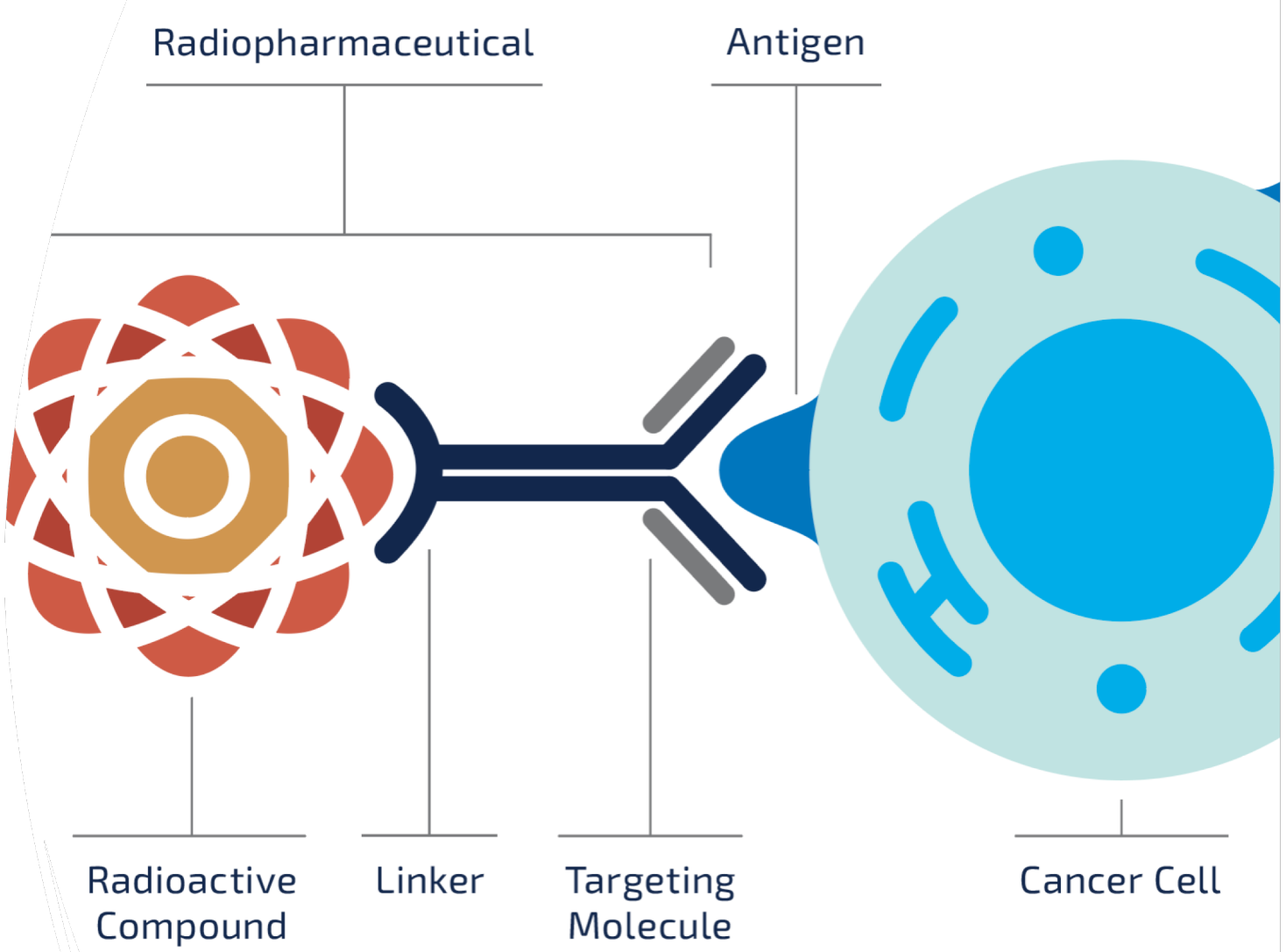


Revolution in Radiation

Targeted Therapies

Radiopharmaceuticals seek out cancer cells throughout the body.

Destroying cancer while leaving healthy cells intact.



Radioisotopes like Actinium-225 are at the forefront of a revolution in treating cancer... but short supplies are limiting research and patient access.

Serva is leveraging proprietary nuclear technology to develop novel production methods, dramatically increase the supply of Ac-225 and other rare isotopes

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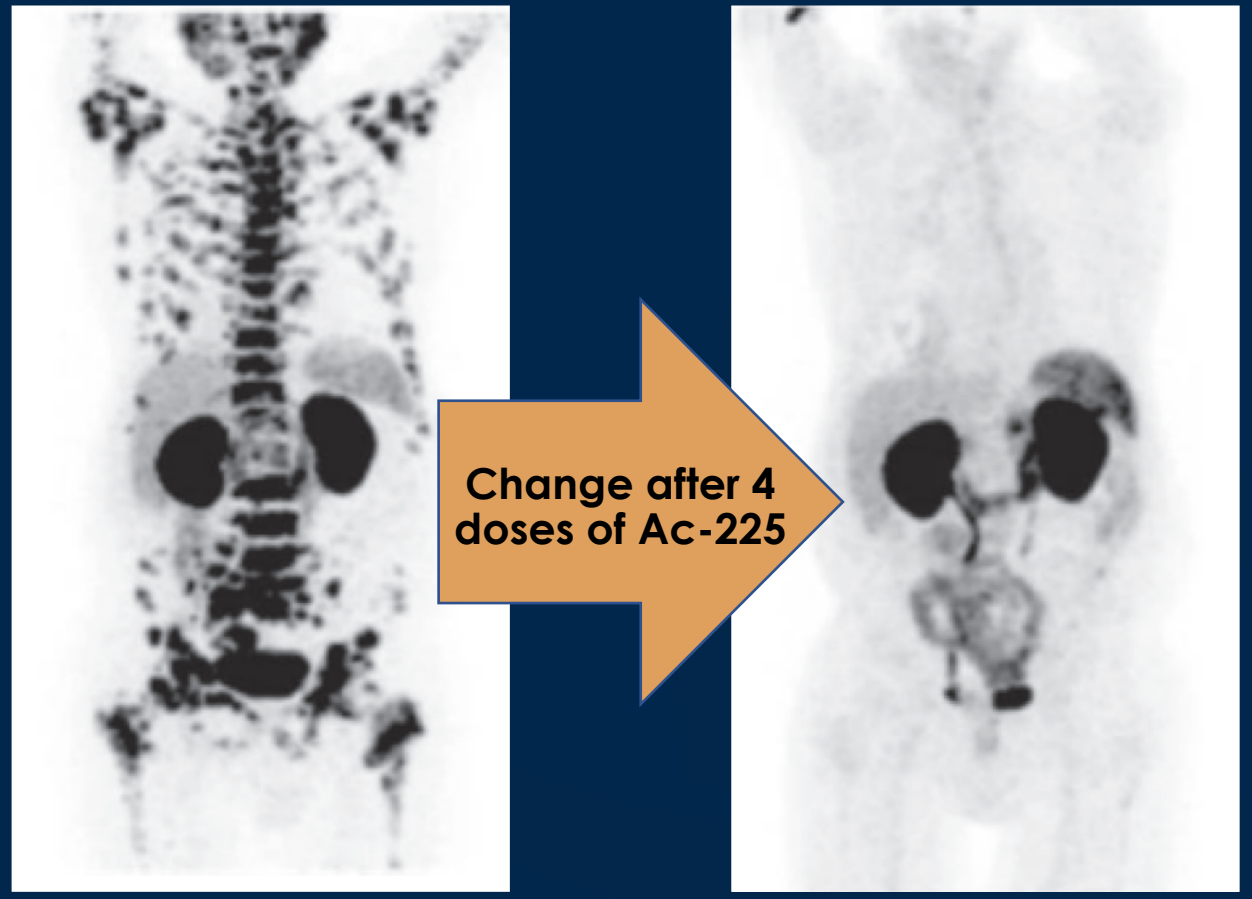
Clinical studies with Ac-225

"Drugs containing Ac 225 have the potential to treat otherwise untreatable cancers"

Dr. Steven Larson, M.D.
Memorial Sloan Kettering Cancer Center



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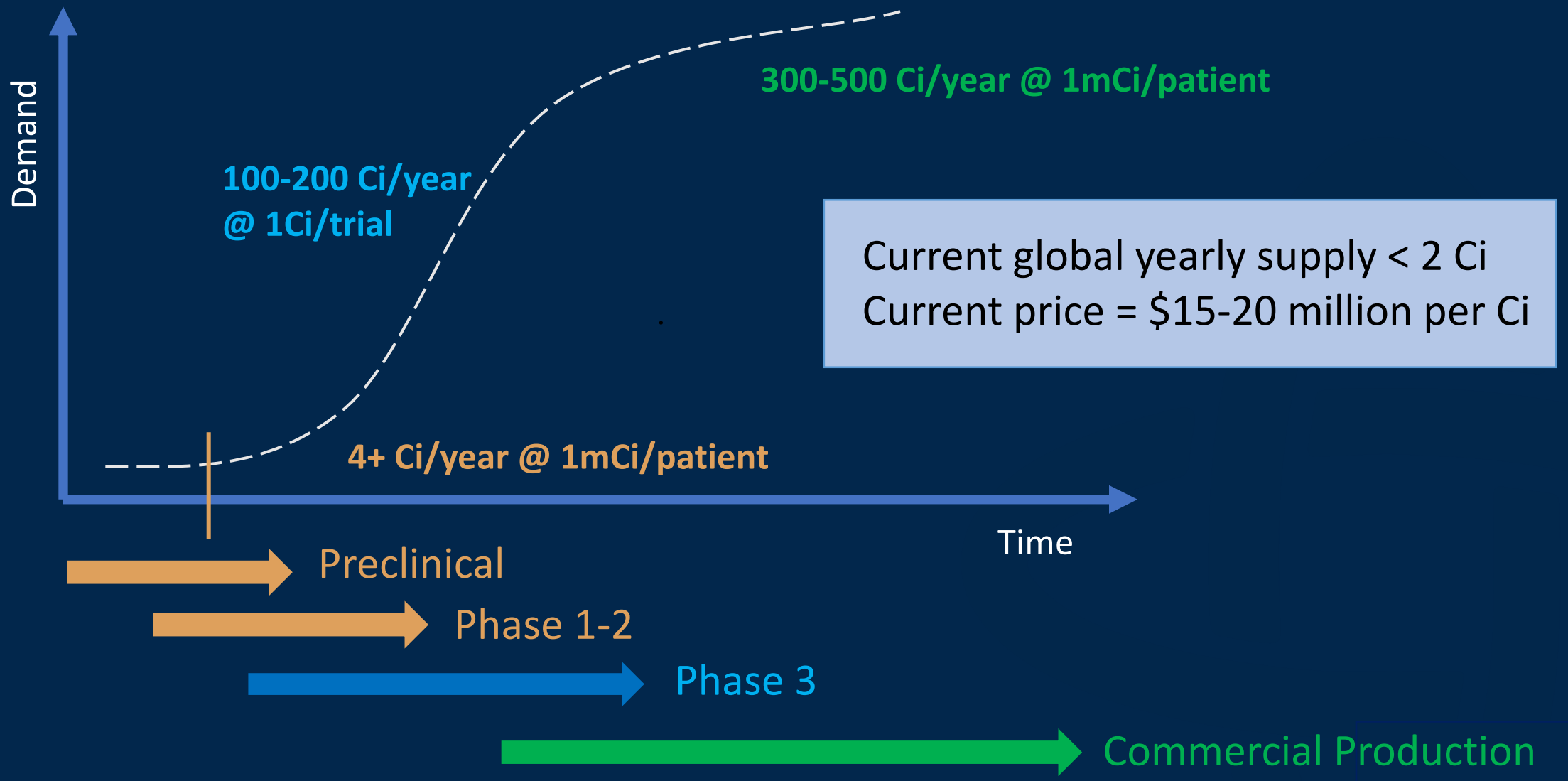
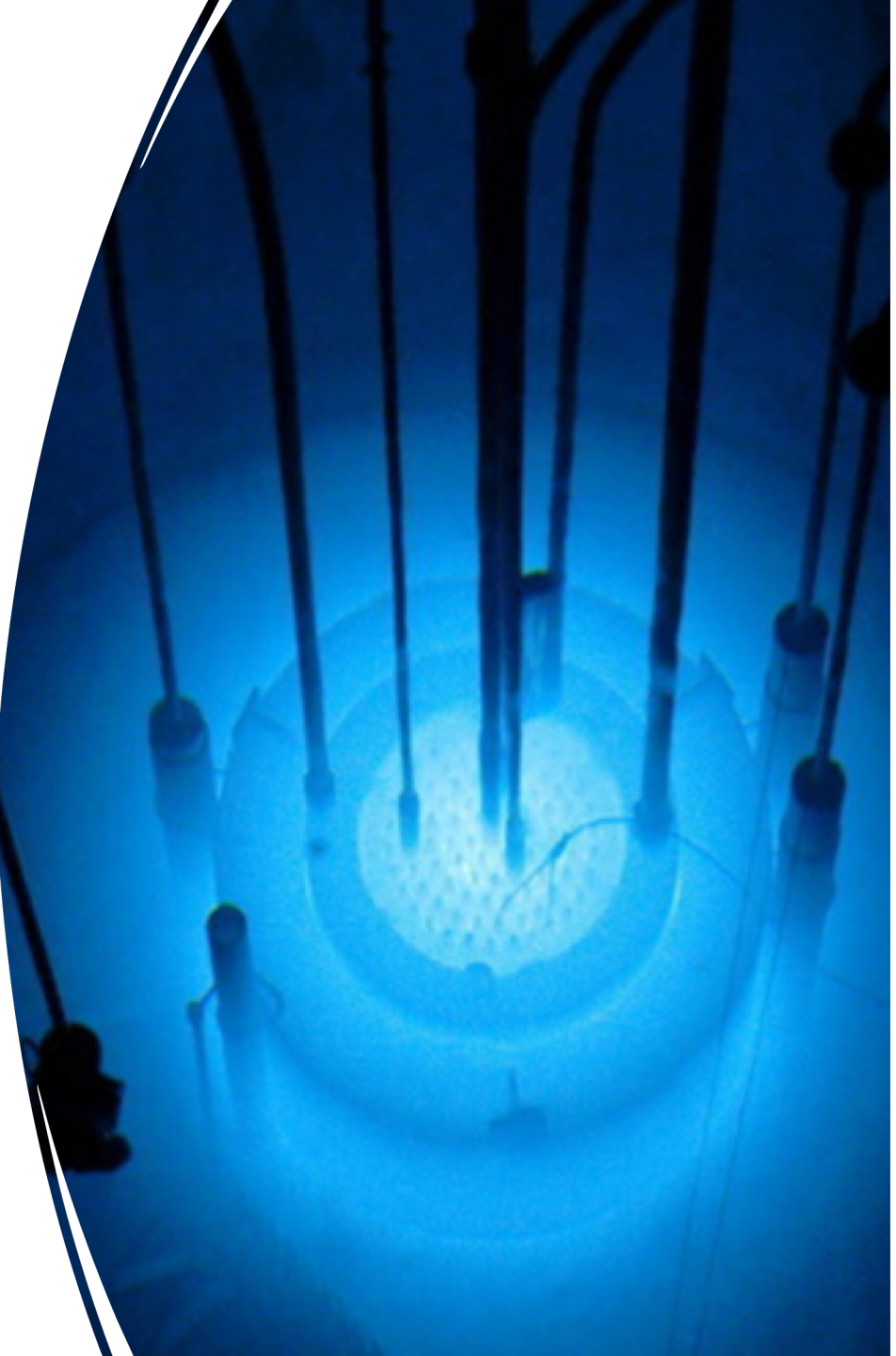
Projected Demand Curve for Ac-225



Current global yearly supply < 2 Ci
Current price = $15-20 million per Ci

Actinium Landscape: Serva is well positioned

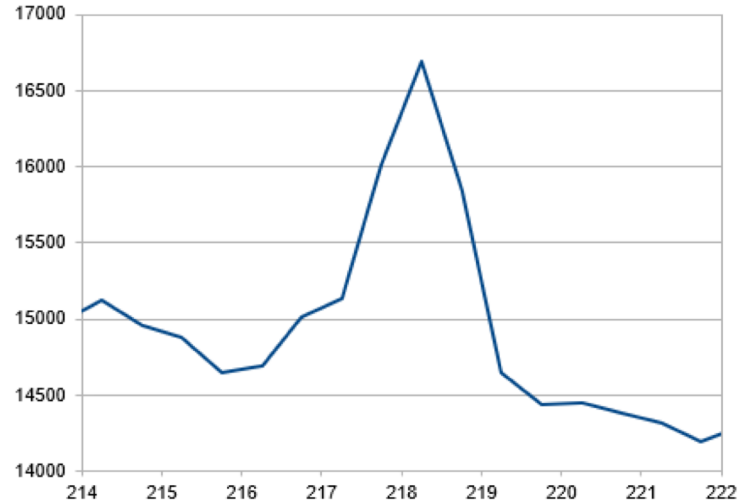
Method	Required infrastructure	Company	Production potential & timing	Limitations
Thorium generator $^{229}Th \rightarrow {}^{225}Ra \rightarrow {}^{225}Ac$	Thorium generator (limited)	• Tri Lab (national labs) • Terra Power	 Available	Supply of ^{229}Th - limited
Thorium spallation ^{232}Th (p,x) $\rightarrow {}^{225}Ac$	Cyclotron	• TRIUMF	 Available	^{227}Ac contamination & waste
^{226}Ra (p,2n)$\rightarrow {}^{225}Ac$	Cyclotron/ High energy	• Ionetix • Alfarim	 2024/2025	Limited production per cyclotron. Scaling requires multiple cyclotrons (higher capital expenses)
^{226}Ra (γ,n) $\rightarrow {}^{225}Ra \rightarrow {}^{225}Ac$	Electron Accelerator	• Northstar • Pantera • Niowave	 2024/2025	High capital expenses with long lead time to production. Ra-226 sourcing
^{226}Ra (γ,n) & (n,2n) $\rightarrow {}^{225}Ra \rightarrow {}^{225}Ac$	Nuclear Reactor	**Serva**	 2023/2024	Uses existing infrastructure. Ra-226 sourcing



Serva Advantage Ac-225 Production

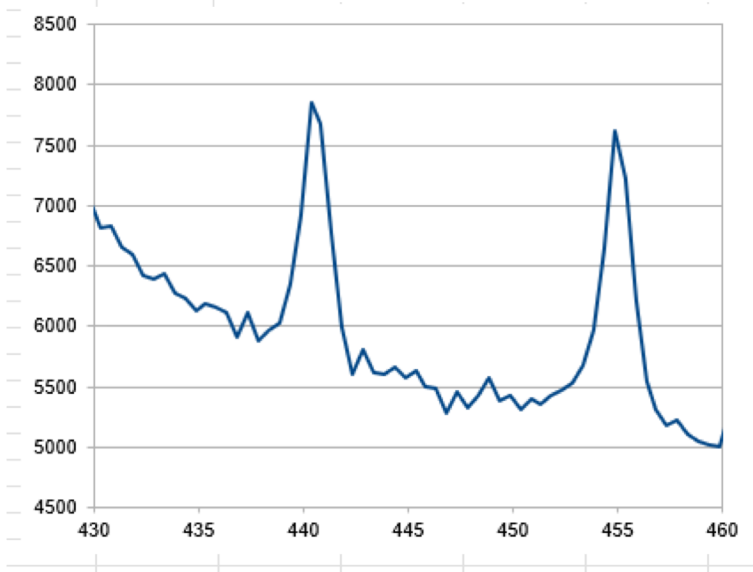
- Serva's SNMs shift the radiation environment to increase the fast neutron flux **in thermal reactors** - needed to drive the (n,2n) reaction
- Existing reactor infrastructure allows production without large capital investment
- Produce significantly greater quantities than current methods
- Indirect method (via Ra-225) allows for "carrier-free" Ac-225 – free of Ac-227 contamination

Breaking News: Serva's New Production Method for Ac-225 Validated



2 daughters of Ac-225

- Fr-221 peak @ 218 keV
- Bi-213 peak @ 440 keV



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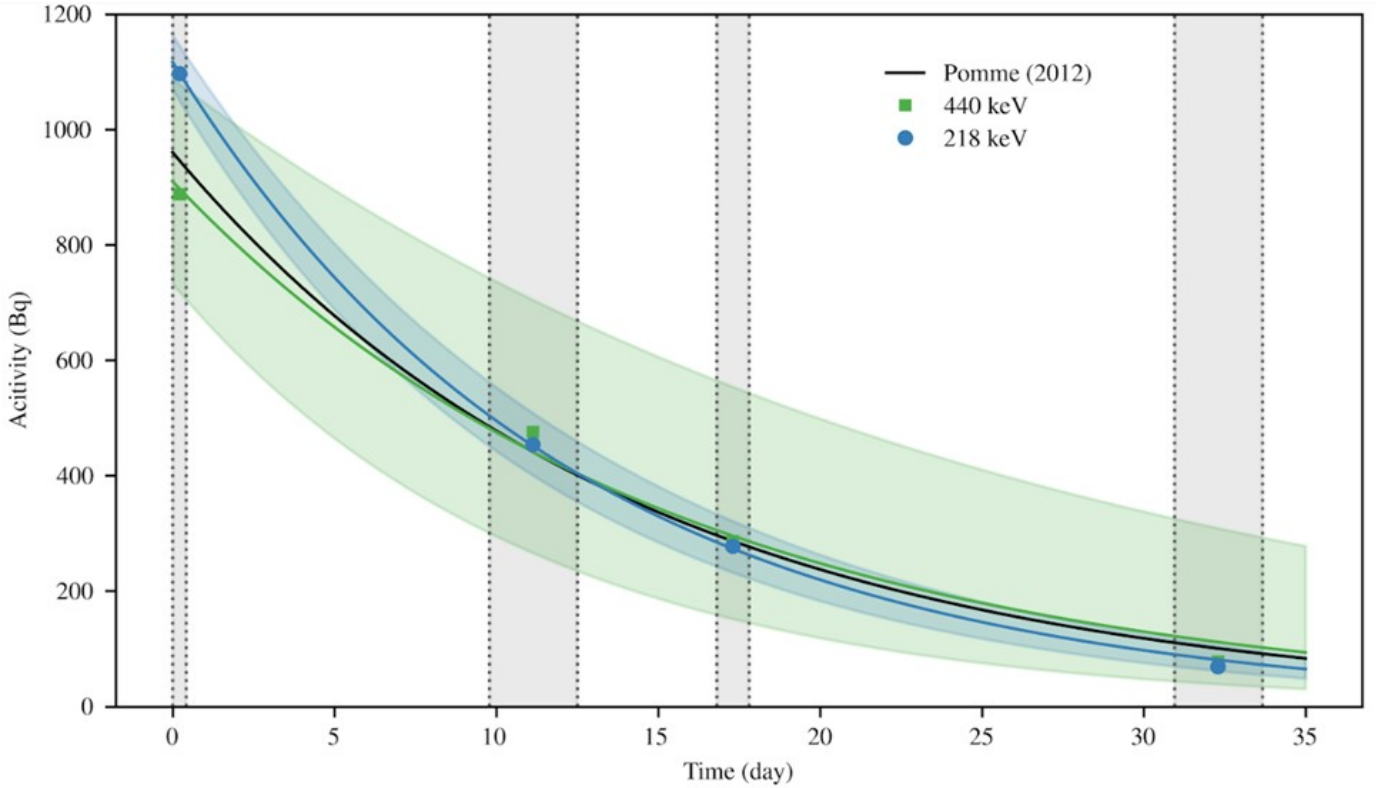

4 sample orientations/geometries – 3 detectors - 2 coasts
Activity normalization of Ra-226

Business Model: Rapid Scaling through Partnership

Serva produces Ac-225 and other isotopes at network of nuclear reactors

Partner with radio-CDMOs to accelerate timeline for production and distribution

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Benefits to Partnering

Industry

- Rapid scaling with existing infrastructure
- Access to academic expertise and equipment
- Increased success with grant opportunities
- Pipeline for workers – students, interns, new hires.

Test Reactor/Universities

- Sustainable revenue
- Collaborative research – faculty/industry
- Increased funding – grant and industry sponsored
- Real-world experiences/employment opportunities for students
- Exposure to cutting edge technology
- Positive press on nuclear

Obstacles to Partnership

Challenges encountered:

- Speed of academia vs industry
- Cumbersome and slow legal/contracting – 6 months (and counting) to get an NDA…..
- Dosimetry for industry partner - ability to effectively conduct experiments
- Complicated fee schedule
- Communication with other partners, universities/gov't entities - sharing RAM licenses, shipping radioactive samples (quickly!)

Industry Needs*

- Operations: 24 hour runs across multiple days (e.g. 5-7 days for Ac-225)
- Power – more is generally better but…
  - UCI is 250kW – great R& D partner!
  - For production, more power=more isotope, but flux enhancements can support lower power (e.g. 1MW)
- Facilities – count rooms, radiochemistry labs, hot cells, analytical tools for use with radioactive materials
- Ease of engagement
  - Work-flow for experiments (SOPs, flexibility - 50.59 & license amendments)
  - Fee schedule – cost per neutron
- Protection of IP

*for Ac-225

Future Development: In-Demand Isotopes

CDMOs and pharmaceutical companies requesting Serva's expertise to develop domestic production of difficult-to-source isotopes

**Co-production with Ac-225 possible and sometimes preferred*

I-131	Mo-99	Lu-177
Tb-161*	Ra-223*	Bi-213*
Cs-131	Th-227*	At-211

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Thank you

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- FPGA driven, 250 MS/s, 16 bit, full data utilization, 100% real-time analytics with new AI-assisted post processing
- Unprecedented resolution and reduced dead time
- Simple, easy to use desk top user interface with cloud processing. Compatible with nearly all detectors
- Significant interest by National labs, nuclear power plants, independent and university-based spectroscopy labs – Beta testing with partners expected Q4, 2023
- Accelerating Serva's development of fuels and isotopes