



7th International Symposium on Medical Radioisotopes

COLD KITS – Beyond SPECT



What are Cold Kits?

Any preparation to be **reconstituted** or combined with **radionuclides** in a radiopharmaceutical product, usually prior to its administration.

ALL BUT THE RADIONUCLIDE



What are Cold Kits?

EU (Dir 2001/83/EC)

API is part of the formulation intended to bind the radionuclide

Dossier:

- Manufacture of the cold kit

- Recommended radiopharmaceutical reconstitution process, radiolabelling performances – Incorporation test

- Specifications of the radionuclide (has to be registered)

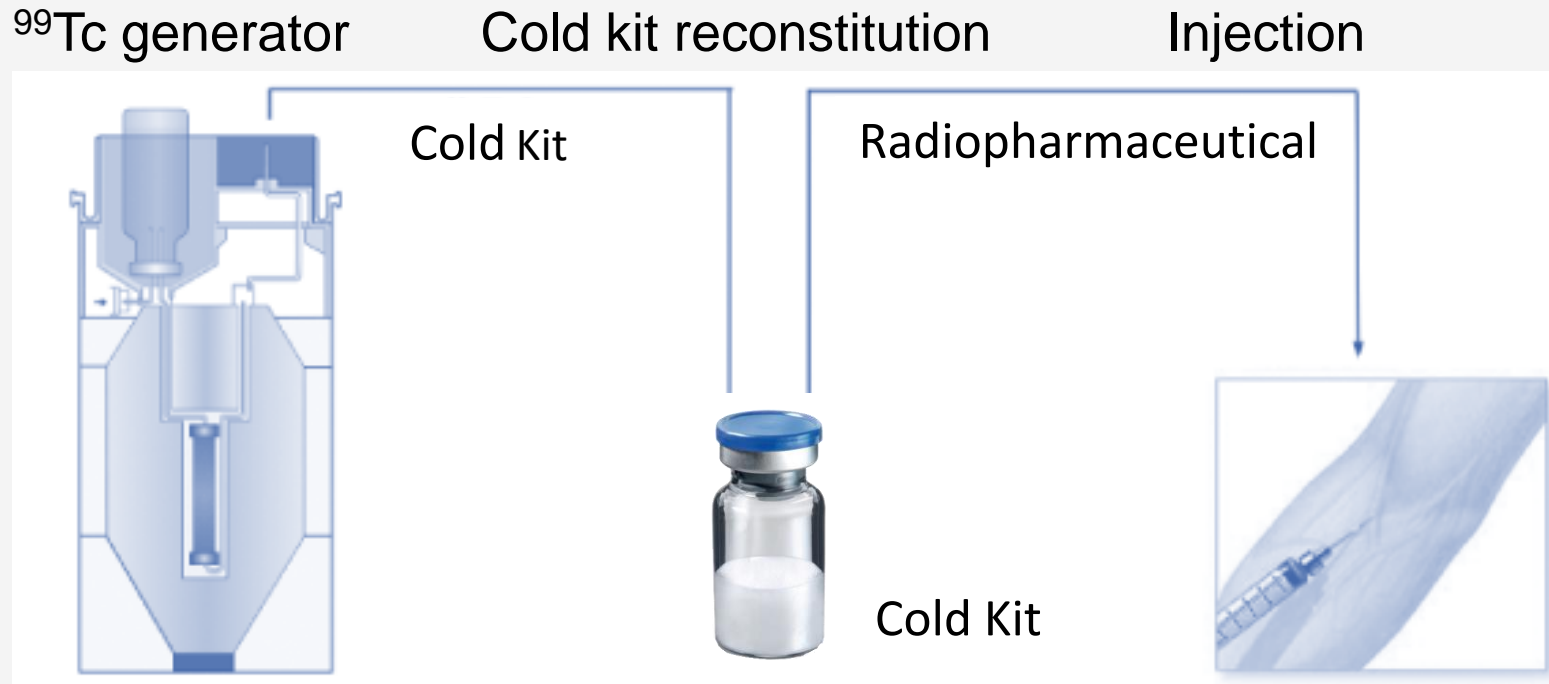
- The structure and specifications of the radiolabelled compound

MA FOR COLD KIT

AND RADIONUCLIDE



SPECT and Tc-99m



The **availability** of a radionuclide **drives** the **development** of radiopharmaceuticals

75% OF NUCLEAR MEDICINE **PROCEDURES**

SPECT and Tc-99m



MANY GENERATORS

SPECT and Tc-99m



MANY COLD KITS

MANY INDICATIONS

Beyond SPECT – Ga-68

Recent availability of registered Ga-68 Generators

First PET cold kit on the market (AAA) for NET

Other cold kits under development including ANMI
PSMA-11 cold kit (Illumet®)

WILL **GALLIUM-68** BE THE
NEXT TECHNETIUM-99?



ANMI/Telix – “Kittification”

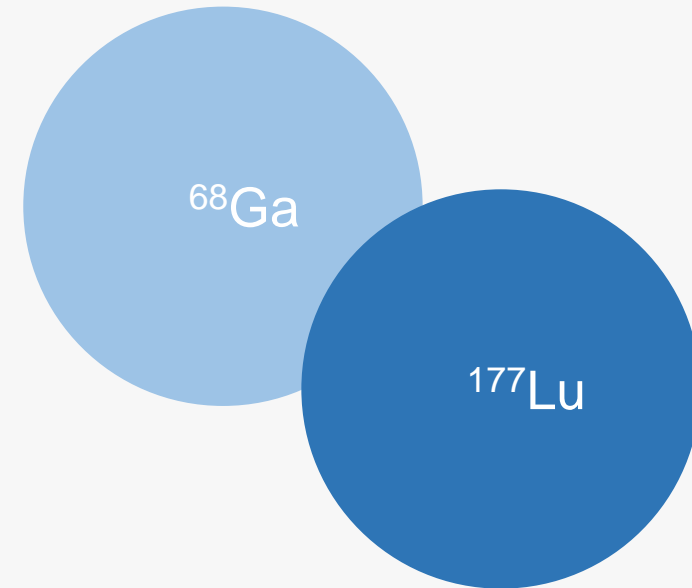
Simple and robust chelation Chemistry

Cost effective

Low regulatory burden

Known clinical practice

Easy to implement



ANMI/Telix – “Kittification”

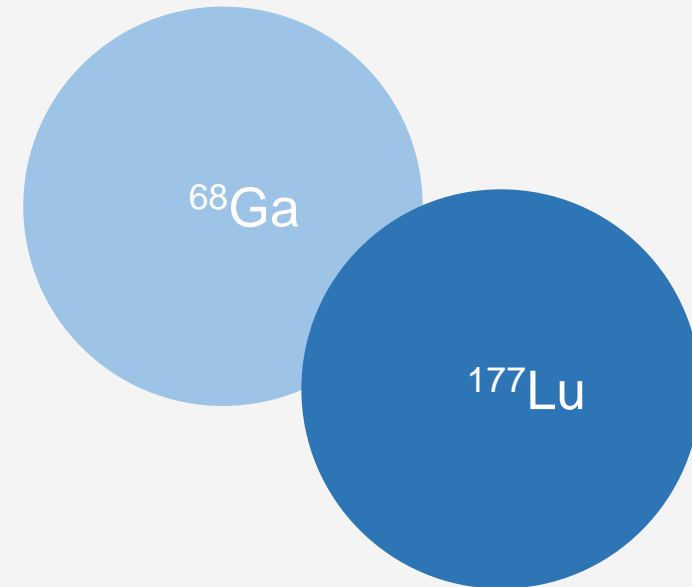
When a radiometal is used

When radiostability is or might be an issue

When the supply chains for the radionuclide is in place

STRAIGHTFORWARD

PATH TO **NEW RADIOPHARMACEUTICALS**



All but the Radionuclide!

Cold kits depends on the radionuclides availability (registration)

Lately, we see a shortage of Ga-68 generators
Demand should raise > 8K/Y by 2022

Thera(g)nostic – Ga-68, Lu-177, Ac-225 and Tc-99m

PHARMA AND **RADIONUCLIDE SUPPLIERS**
MUST **WORK TOGETHER**



To Take back Home

COLD KITS SHOULD BE CONSIDERED IN
RADIOMETAL-BASED
RADIOPHARMACEUTICALS DEVELOPMENT



COLD KITS NEED RADIONUCLIDES
WE MUST **WORK TOGETHER** TO **FACE AND**
ANTICIPATE THE NEEDS

A word cloud featuring the word "THANK YOU" in large, bold, blue capital letters. Surrounding it are various translations of "Thank You" in different languages, including: GRACIAS, ARIGATO, SHUKURIA, GOZAIMASHITA, EFCHARISTO, FAKAAUE, KOMAPSUMNIDA, MAAKE, LAH, GRAZIE, MEHRBANI, PALDIES, BOLZÏN, MERCI, DANKSCHEEN, SPASSIBO, SNACHALHUYA, NUHUN, CHALTU, YAQHANYELAY, TASHAKKUR ATU, WABEEJA, MATTEKA, HUI, YUSPAGARATAM, SUKSAMA, EKHMET, SPASIBO, DENKAUJA, HENACHALHYA, UNALCHEESH, HATUR, GUR, TINGKI, BİYAN, SHUKRIA, MAKETAJ, MINMONCHAR, and AXAR. The word cloud is set against a white background with a blue diagonal stripe at the bottom.

