Radiopharmaceutical Education for Patients & Physicians

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16.6M CHILDREN AND ADULTS WITH CANCER RECEIVE TREATMENT AND ARE CANCER SURVIVORS

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50% of cancer survivors who received treatment underwent radiotherapy.

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NCI PROGRAMMATIC INITIATIVES WILL BOOST RADIOPHARMACEUTICAL CLINICAL DEVELOPMENT USING

10 TREATMENT ARMS

300+ NCI-AUDITED SITES

2020-2021
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NCI PROGRAMMATIC INITIATIVES WILL TEST 7+ RADIOPHARMACEUTICALS IN CLINICAL DEVELOPMENT 2020-2021 TO APPEAL TO PATIENTS AND TO BROADEN CLINICAL UTILITY
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2% OF CLINICAL TRIALS USE RADIOPHARMACEUTICALS IN THE UNITED STATES NOW

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60% of radiotherapy trials to use radiopharmaceuticals in the next 10-15 years

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NCI considers radiopharmaceuticals as drugs because they have anti-cancer drug-like properties such as:

- Having predictable organ toxicities
- Having quantifiable pharmacokinetics
- Having prescriptions fixed by body weight
- Emitting radiation that overwhelms a cancer cell’s DNA damage response to kill cancer cells

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Radiopharmaceuticals target cancer cells and kill them.

cancer cell

radiopharmaceutical

cancer cell

dead cancer cell

INFUSED

INHALED

INGESTED

INJECTED
A hallmark of cancer cells is the loss of one or more DNA damage responses that are a hallmark of cancer cells is the loss of one or more DNA damage responses that are.

Radiopharmaceuticals exploit.

Cancer cells overreliant on one response are more prone to die when it is blocked.

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National Cancer Institute Programmatic Collaboration for Investigational Radiopharmaceuticals.
NCI CONSIDERS RADIOPHARMACEUTICALS AS DRUGS WHOSE EMISSIONS DURING THEIR DECAY DAMAGE CANCER CELL DNA

THERE ARE FOUR TYPES OF EMISSIONS:

1. helium nucleus (α particle)

2. electron (β particle)

3. Auger electron

4. photon

CANCER CELLS UNCOORDINATED IN THEIR DNA DAMAGE RESPONSE ONCE IRRADIATED ARE PRONE TO DIE

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NCI considers radiopharmaceuticals as drugs whose emissions during their decay damage cancer cell DNA.

DNA strand breaks are lethal to cancer cells:

1. Damage can occur.
2. Ribonucleotide reductase (RNR) makes de novo deoxyribonucleotides.
3. Unrepaired DNA.

IRRADIATED NORMAL CELLS SURVIVE WHEN THEIR DNA DAMAGE RESPONSE FIXES STRAND BREAKS.

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RANGE & POTENTIAL TOXICITY:

1. Helium nucleus (α particle)
   - 10 cancer cell diameters

2. Electron (β particle)
   - 27 cancer cell diameters

3. Conversion electron (Auger electron)
   - 21 cancer cell diameters
NCI INVESTMENT IN RADIOPHARMACEUTICAL CLINICAL DEVELOPMENT INVOLVES:

- SCIENTIFIC REVIEW BY RADIOPHARMACEUTICAL EXPERTS
- RADIOPHARMACEUTICAL HANDLING
- RADIOPHARMACEUTICAL MEDICAL MONITORING

INNOVATIVE TRIAL DESIGNS

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NCI IS IN A STRONG POSITION TO PROVIDE INFRASTRUCTURE BUILDS FOR RADIOPHARMACEUTICAL CLINICAL TRIALS BECAUSE OF:

- Established means for new investigator registration
- Web-based monitoring interfaces
- Established agent shipping & handling procedures

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INNOVATIVE TRIAL DESIGNS USE:

PHASE 0 TRIALS TEST MARKERS

Evaluate prespecified biomarker change within one subject after a fixed dose and schedule, then

Evaluate prespecified biomarker change within a population after a fixed dose and schedule

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Phase 1 Trials to Test Safety

Innovative Trial Designs Use:

- **Radiopharmaceutical A**: 1 or less of 6 patients have toxicity at a dose & schedule: safe dosimetry

- **Radiopharmaceutical B**: 2 or more of 6 patients have toxicity at a dose & schedule: unsafe dosimetry

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**RADIOPHARMACEUTICAL**

**INNOVATIVE TRIAL DESIGNS USE:**

**PHASE 2 TRIALS TO TEST EFFICACY**

recist 1.1 waterfall plot for efficacy

[Diagram showing recist 1.1 waterfall plot for efficacy with labels for progression, response, and dimension (%).]

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NCI REGISTERS OVER 1,100+ AUTHORIZED USERS ANNUALLY INTENDING RADIOPHARMACEUTICAL ADMINISTRATION FOR MEDICAL USE BY RADIATION ONCOLOGISTS OR NUCLEAR MEDICINE PHYSICIANS IN FY 2020 ctep.cancer.gov/investigatorResources
FOR NCI-SPONSORED TRIALS

300+

WRITTEN DIRECTIVES WILL BE

VERIFIED FOR RADIOPHARMACEUTICAL

ADMINISTRATION FOR MEDICAL USE EACH YEAR BY

RADIATION ONCOLOGISTS

OR NUCLEAR MEDICINE

PHYSICIANS BEGINNING IN 2020

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NCI WILL VERIFY UP TO 2,200 RADIOACTIVE MATERIAL LICENSES INTENDING RADIOPHARMACEUTICAL ADMINISTRATION BY PHYSICIANS AT ITS TRIAL SITES FOR CLINICAL TRIALS BEGINNING FY 2020

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NCI WILL REQUIRE TRAINING FOR RADIOPHARMACEUTICAL USE AMONG ITS 1,100 PHYSICIAN INVESTIGATORS IN FY 2020-2021

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NCI WILL CREDENTIAL 140+ RADIOPHARMACIES OR ‘HOT LABS’ AMONG ITS CLINICAL TRIAL SITES IN FY 2020-2021 FOR USE OF RADIOPHARMACEUTICALS

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NCI PLANS TO REGISTER

2+

RADIATION SAFETY OFFICERS OR OTHER QUALIFIED PERSONNEL

AT EACH CLINICAL TRIAL SITE WHERE RADIOPHARMACEUTICAL ADMINISTRATION IS INTENDED FOR MEDICAL USE IN FY 2020-2021

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IN ITS SPONSORED TRIALS
NCI WILL REQUEST

3 MEASUREMENTS OF RADIOPHARMACEUTICAL RADIOACTIVITY:

- AT INITIAL SHIPMENT
- AT INITIAL RECEIPT
- AT ADMINISTRATION

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1 DELEGATION OF TASK LOG IDENTIFYING AN:

- AUTHORIZED USER PRESCRIBER
- AUTHORIZED USER DRUG MAILER
- AUTHORIZED USER FOR MEDICAL USE

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