Radiopharmaceutical Education for Patients & Physicians

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NIH NATIONAL CANCER INSTITUTE

May 8, 2020

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

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National Cancer Institute Programmatic Collaboration for Investigational Radiopharmaceuticals.
Kunos CA, Capala J. Am Soc Clin Oncol Educ Book. 2018 May 23;38:488–494. doi: 10.1200/EDBK_200199

50% OF CANCER SURVIVORS

WHO RECEIVED TREATMENT

UNDERWENT RADIOTHERAPY

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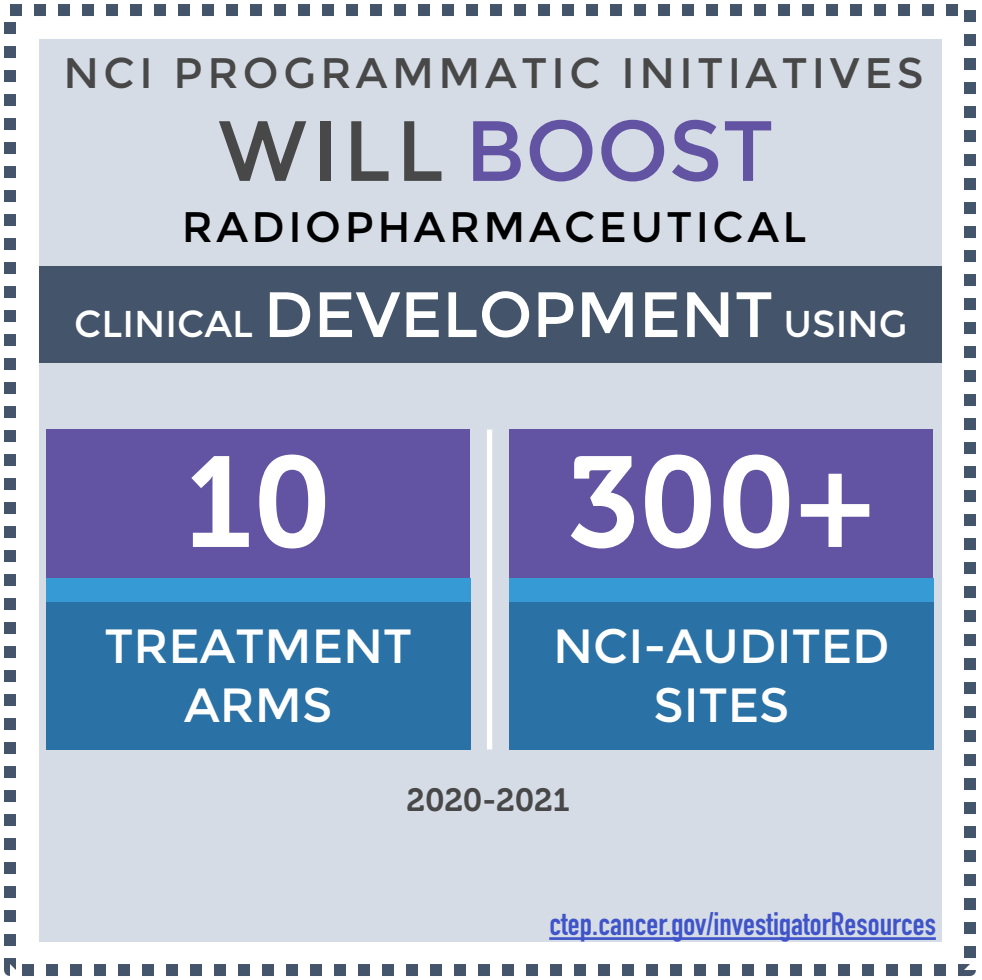

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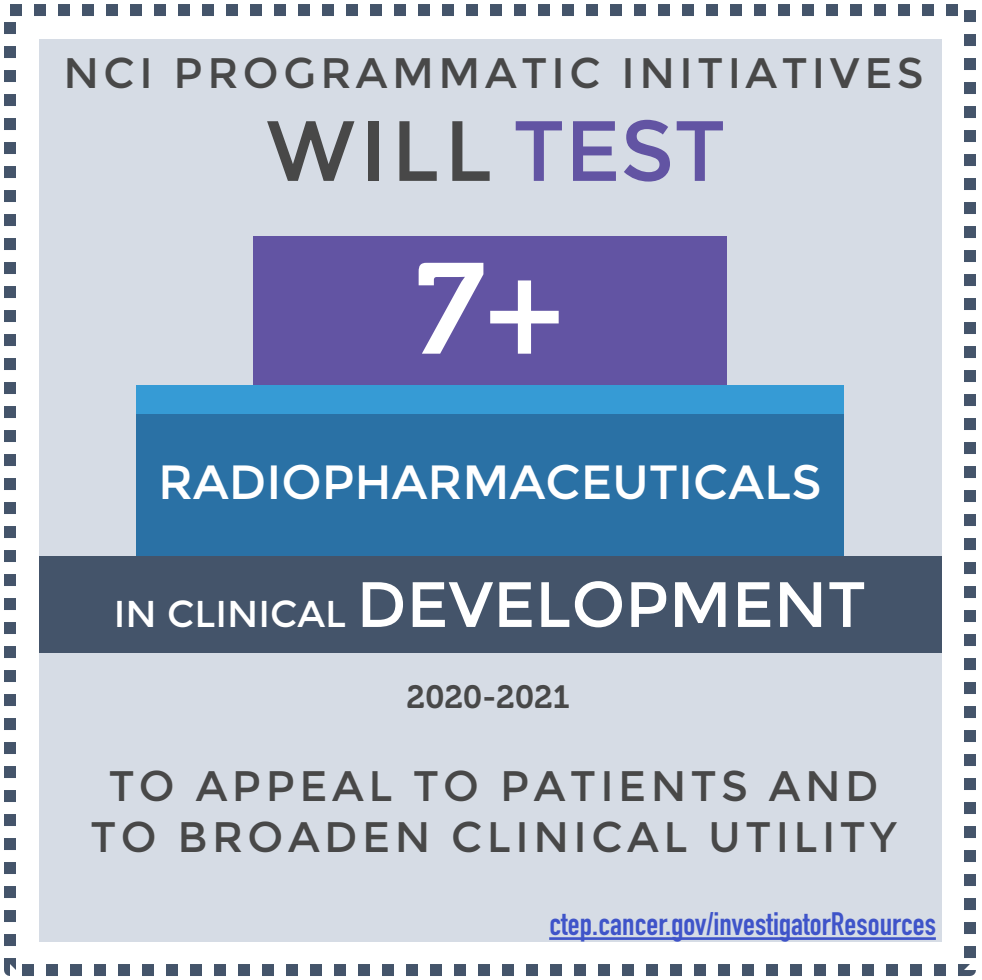

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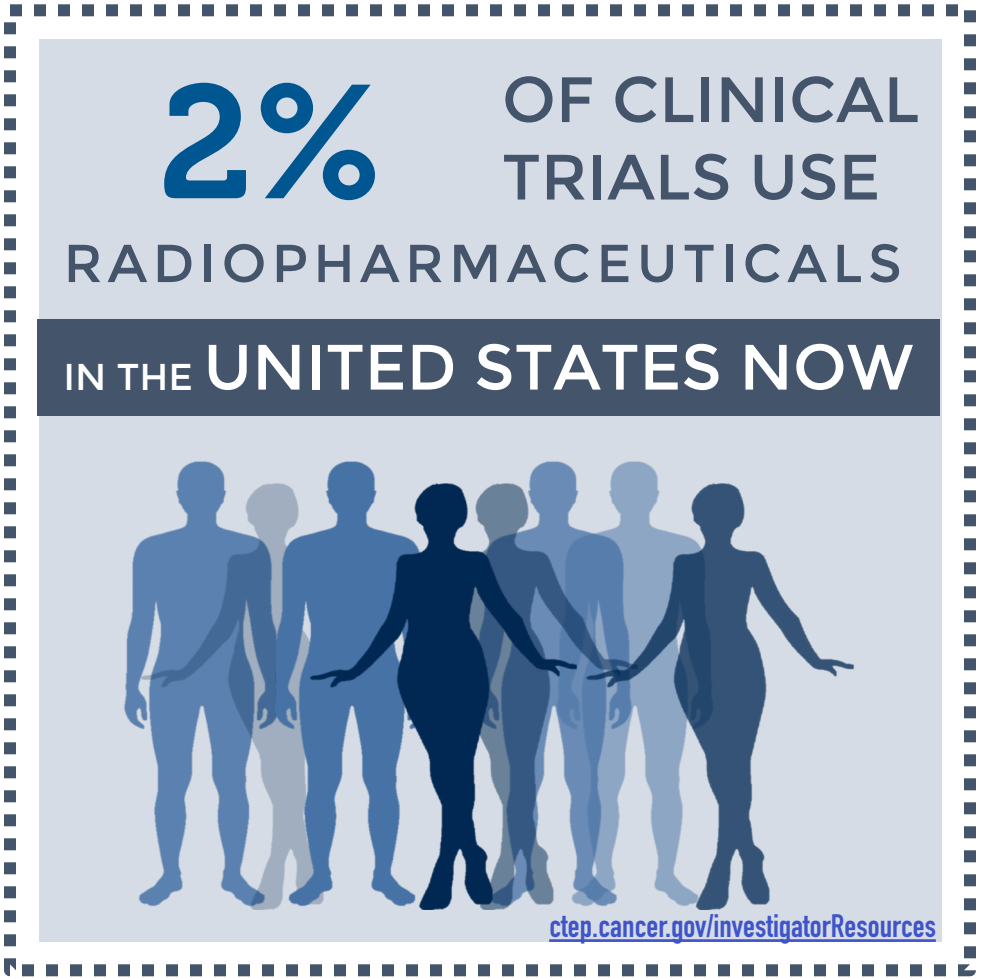

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60% OF RADIOTHERAPY TRIALS TO USE RADIOPHARMACEUTICALS

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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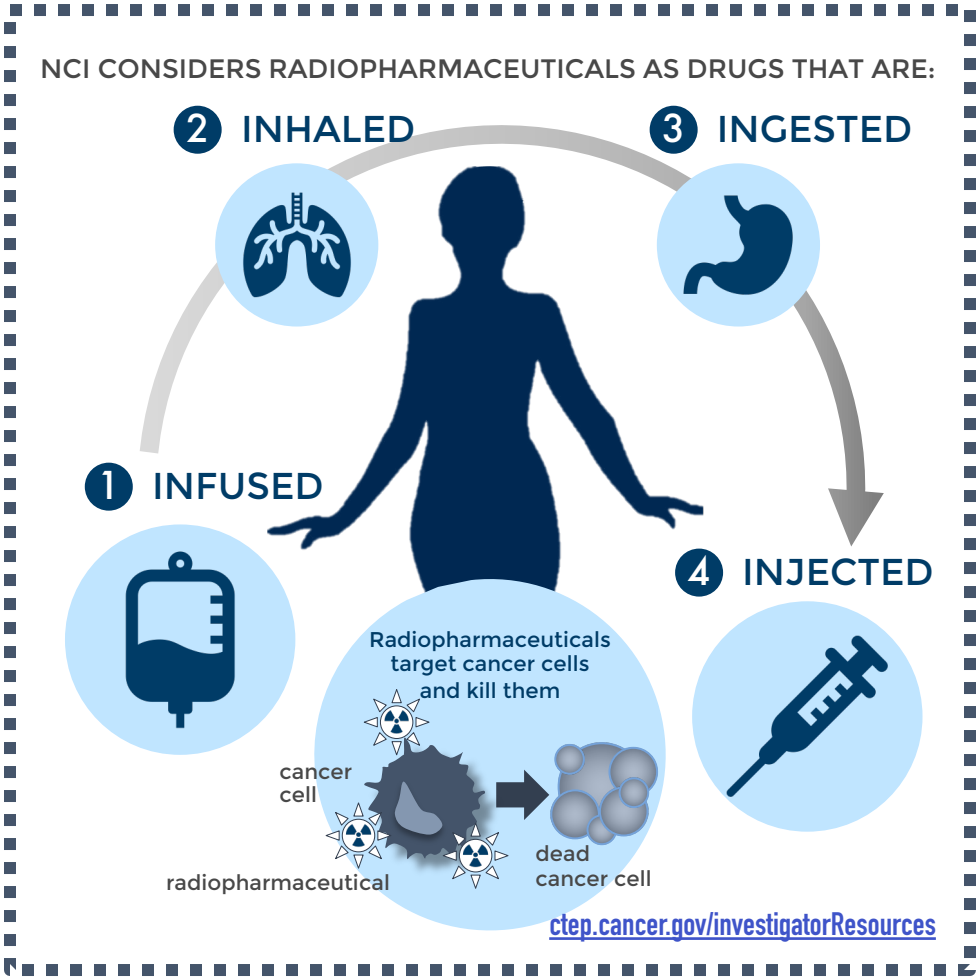

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A HALLMARK OF CANCER CELLS IS THE LOSS OF ONE OR MORE

DNA DAMAGE RESPONSES THAT

RADIOPHARMACEUTICALS EXPLOIT

CANCER CELLS OVERRELIANT ON ONE RESPONSE ARE MORE PRONE TO DIE WHEN IT IS BLOCKED

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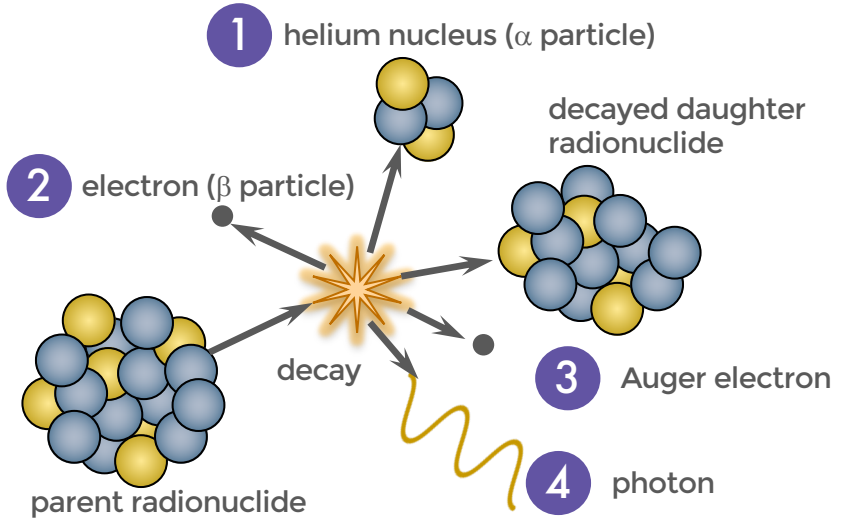
NCI CONSIDERS RADIOPHARMACEUTICALS AS DRUGS WHOSE

EMISSIONS DURING THEIR DECAY

DAMAGE CANCER CELL DNA

THERE ARE FOUR TYPES OF EMISSIONS:



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

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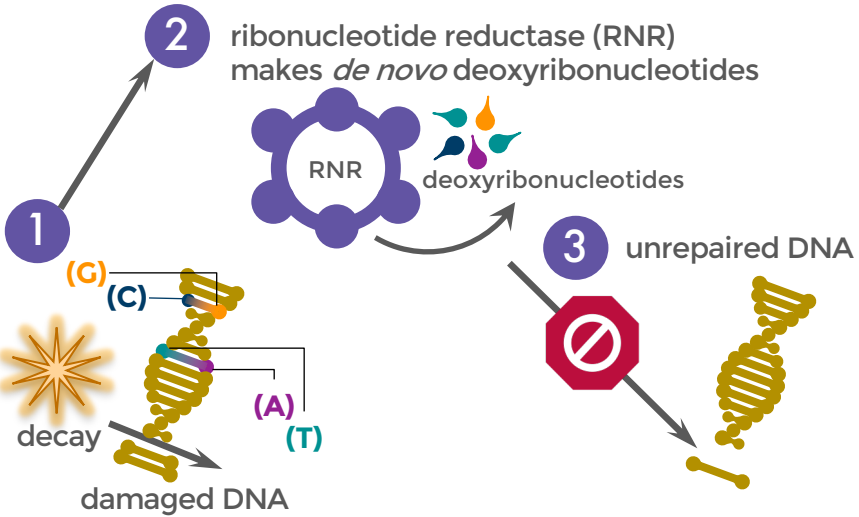
NCI CONSIDERS RADIOPHARMACEUTICALS AS DRUGS WHOSE

EMISSIONS DURING THEIR DECAY

DAMAGE CANCER CELL DNA

DNA STRAND BREAKS ARE LETHAL TO CANCER CELLS:



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

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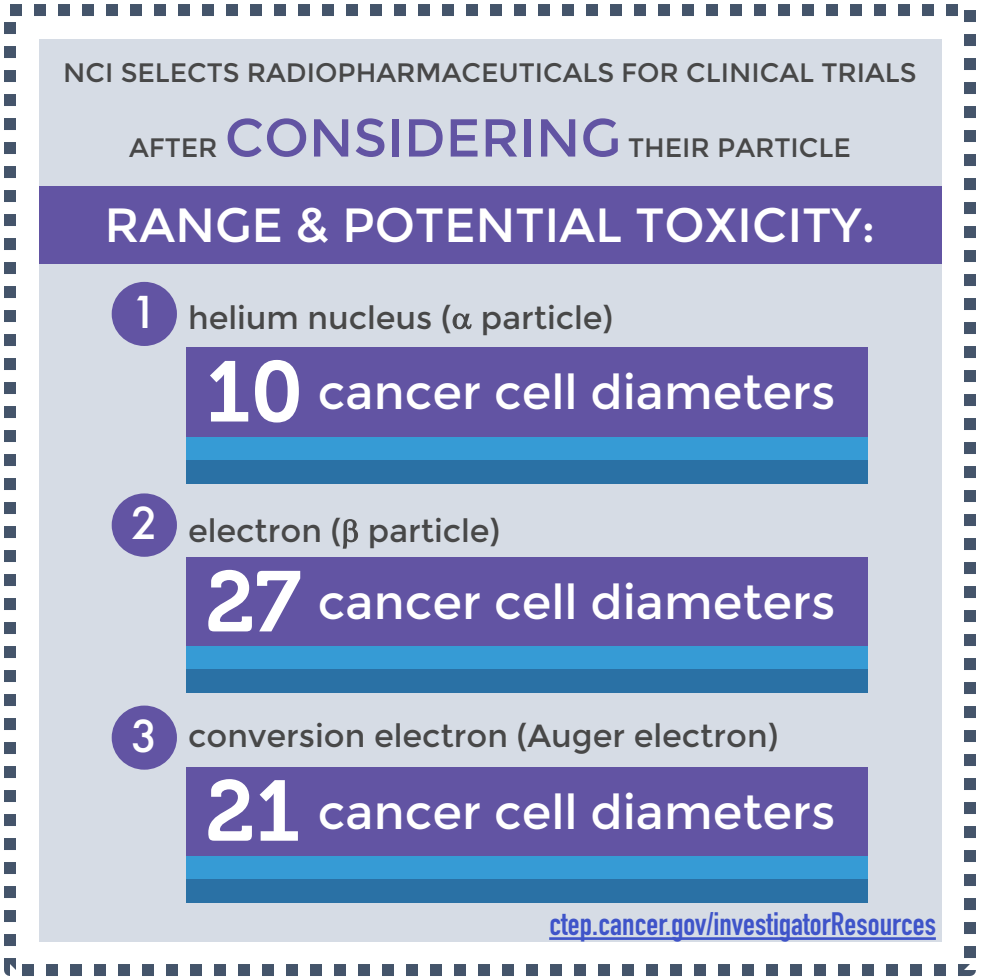

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NCI INVESTMENT IN RADIOPHARMACEUTICAL CLINICAL DEVELOPMENT INVOLVES:

SCIENTIFIC REVIEW BY RADIOPHARMACEUTICAL EXPERTS

RADIOPHARMACEUTICAL HANDLING

RADIOPHARMACEUTICAL MEDICAL MONITORING

INNOVATIVE TRIAL DESIGNS

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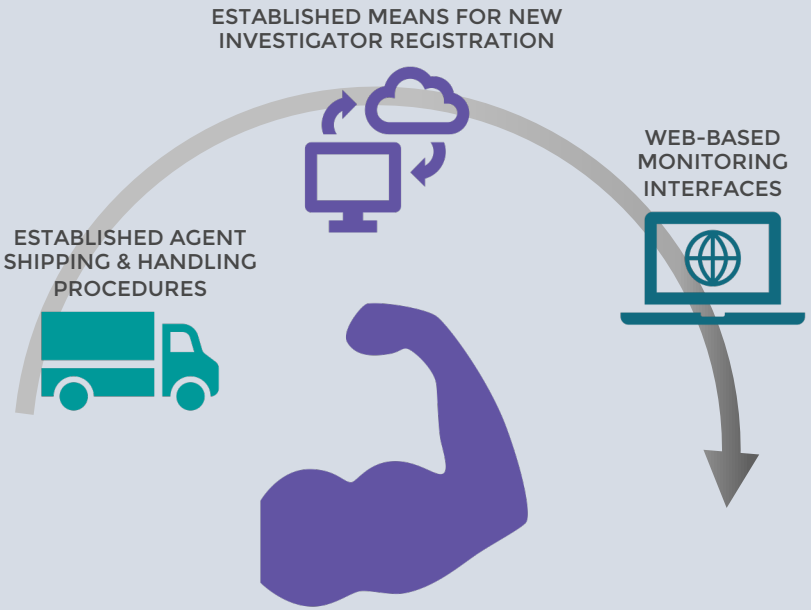
NCI IS IN A STRONG POSITION TO PROVIDE

INFRASTRUCTURE BUILDS FOR

RADIOPHARMACEUTICAL CLINICAL TRIALS BECAUSE OF:



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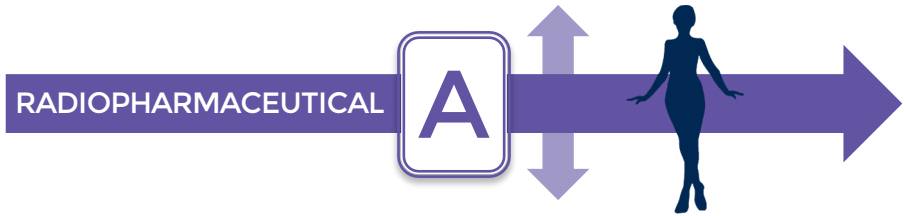
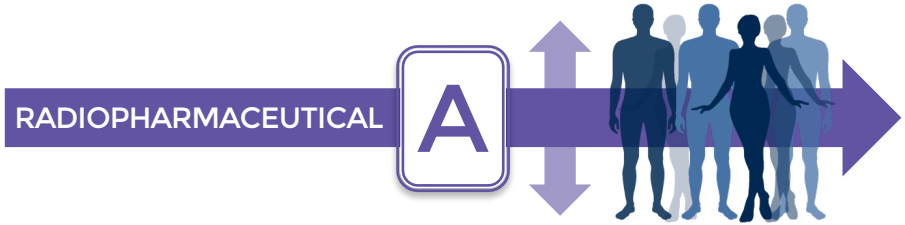
RADIOPHARMACEUTICAL

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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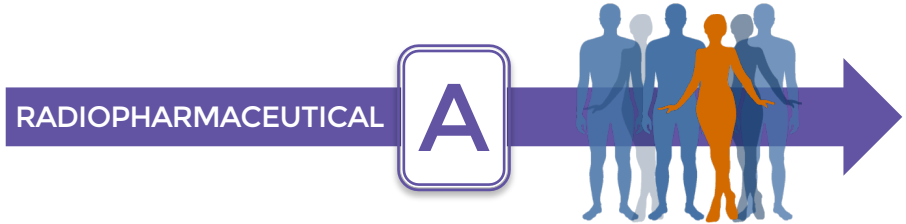
Radiopharmaceuticals for Relapsed or Refractory Ovarian Cancers. Kunos CA, Capala J, Finnigan S, Smith GL, Ivy SP. Front Oncol. 2019 Mar 26;9:180. doi: 10.3389/fonc.2019.00180. eCollection 2019

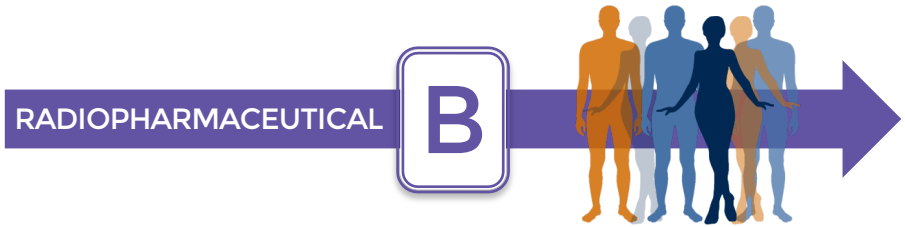
RADIOPHARMACEUTICAL

INNOVATIVE TRIAL DESIGNS USE:

PHASE 1 TRIALS TO TEST SAFETY



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



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

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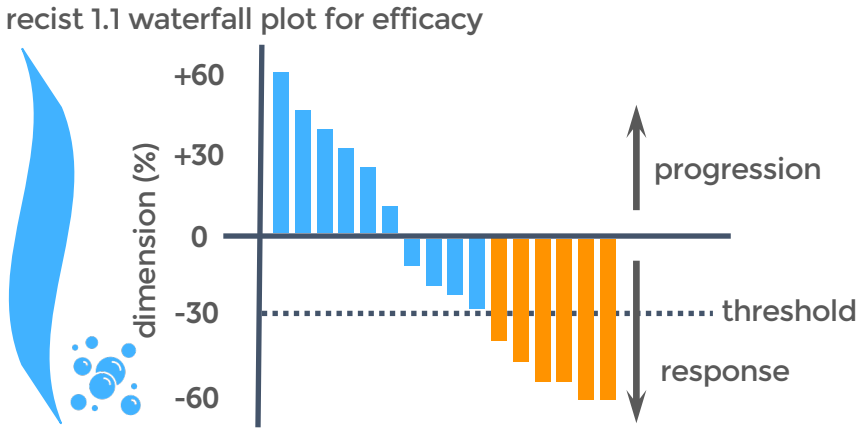
RADIOPHARMACEUTICAL

INNOVATIVE TRIAL DESIGNS USE:

PHASE 2 TRIALS TO TEST EFFICACY



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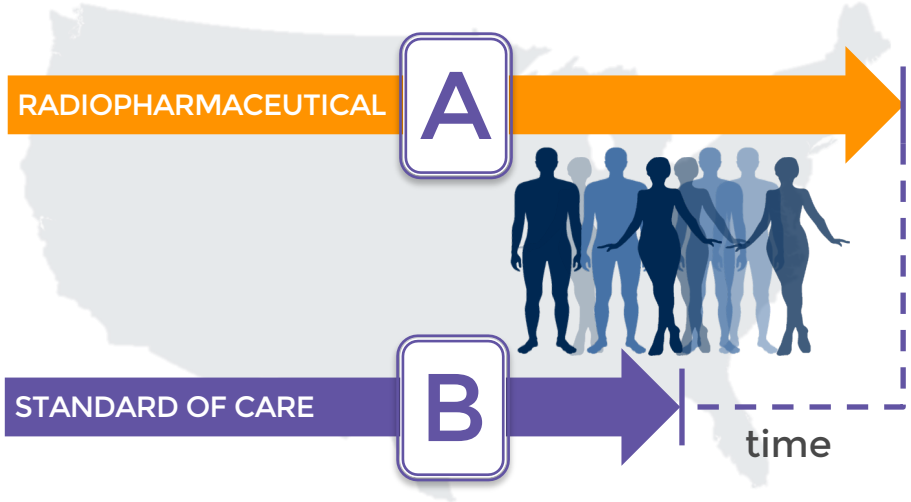
RADIOPHARMACEUTICAL

INNOVATIVE TRIAL DESIGNS USE:

PHASE 3 TRIALS TO TEST SURVIVAL



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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

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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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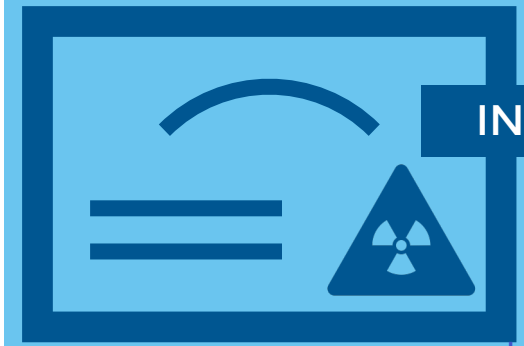
NCI WILL REQUIRE TRAINING
FOR RADIOPHARMACEUTICAL USE AMONG ITS

1,100

PHYSICIAN INVESTIGATORS



IN FY 2020-2021

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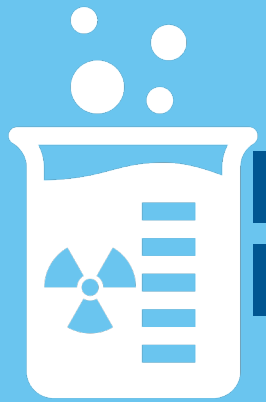
NCI WILL CREDENTIAL

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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RADIOPHARMACEUTICAL
NCI-SPONSORED TRIALS USE

1 DELEGATION OF TASK LOG IDENTIFYING AN:

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

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