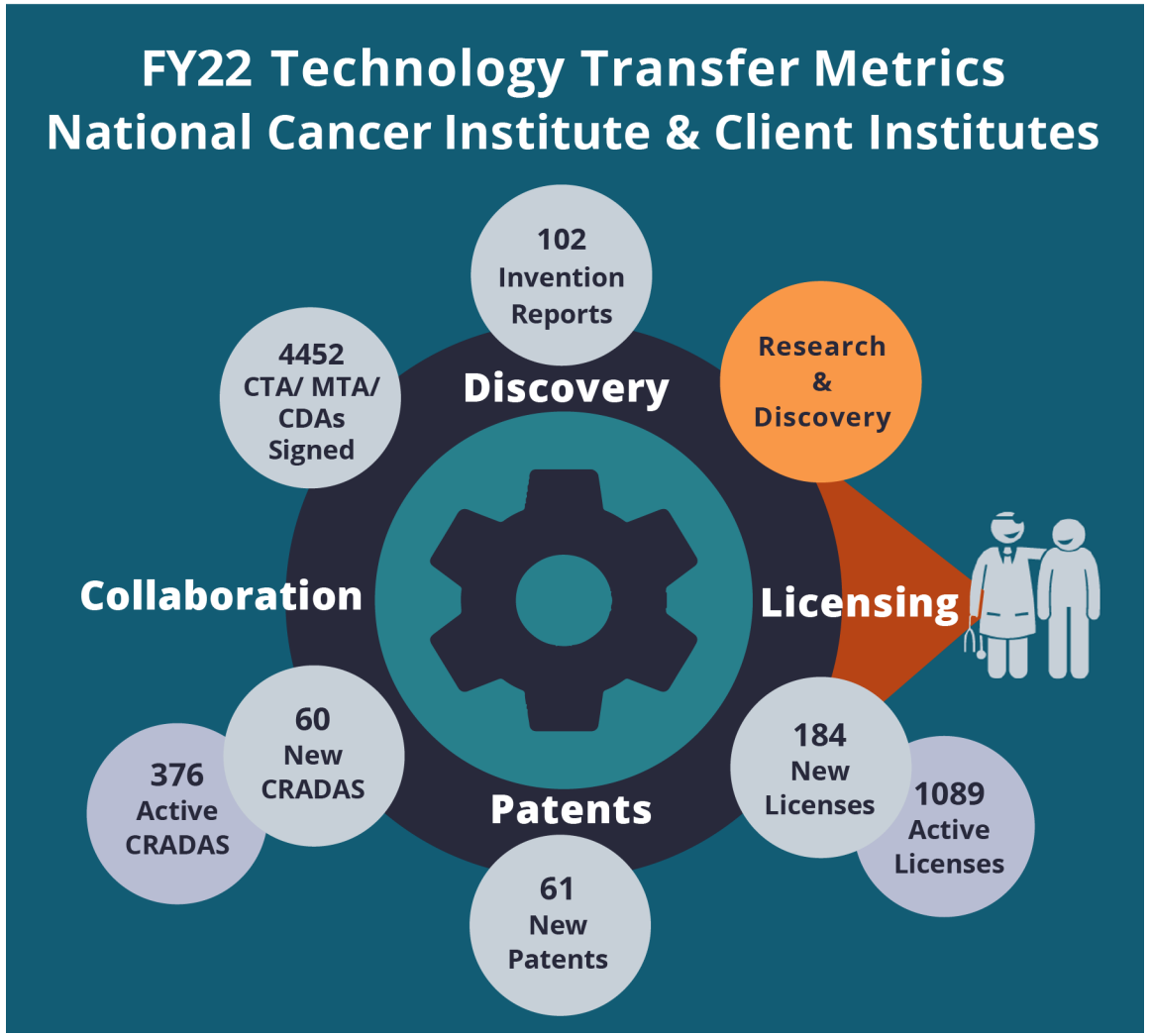
Collaboration Agreements

Multi-Cancer Detection (MCD) Assay Studies



NCI Partnerships & Collaborations

Advantages:

- Access to unique resources
- Access to world-renowned scientific and regulatory expertise
- No equity position
- Won't take your IP

Agreements

- Document obligations and legal liabilities of the parties
- To protect interests/rights of the parties
- Help avoid future disagreement between the parties

Types of Agreements

- **Confidential Disclosure Agreement**
  - Protects exchange of non-public information/data between NCI and the Assay Developer
  - Established with Developers in anticipation of participation in the MCD Studies
- **Human material – Material Transfer Agreement (Hm-MTA)**
  - Specifies transfer of research materials (human samples) and data
    - Documents origin and ownership of materials and data, limitations on use and distribution of materials and data, publication, confidentiality obligations, etc.
  - Established prior to Developer's participation in the Performance Verification Process
- **Clinical Collaboration Agreement**
  - A more extensive Hm-MTA; may contain up-front licensing options
  - Established prior to Developer's participation in the Vanguard and any future CSRN studies

MCD Assay Agreements

Stage 1: PERFORMANCE VERIFICATION PROCESS

- Conducted by Assay Developers using NCI-provided reference samples
- Developers to provide NCI with resulting data

Human Material-Material Transfer Agreements

Timeline ~ 4-8 weeks

Stage 2: VANGUARD

- Conducted by clinical sites under NCI's Cancer Screening Research Network (CSRN)
- Study data will be made available to Developers

Clinical Collaboration Agreements

Timeline ~ 6 months

Stage 3: CSRN STUDIES (*future*)

- Conducted by clinical sites under NCI's Cancer Screening Research Network (CSRN).
- Study data will be made available to Developers

Clinical Collaboration Agreements

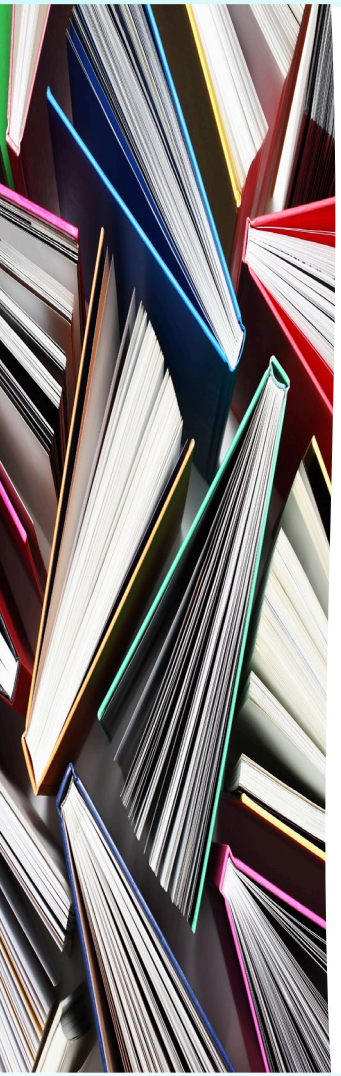
Timeline ~ 6 months

- ❖ An agreement will be established between NCI and Assay Developer prior to its participation in a given study.
- ❖ Developer does not have to establish any agreements with the CSRN clinical sites.
- ❖ Agreements will be negotiated and managed by NCI Technology Transfer Center.

Major Provisions in Agreements

- The terms of the agreement will govern the collaboration between the Assay Developer and NCI
- General NCI policies related to:
  - ❖ Publications
  - ❖ Data Rights
  - ❖ Intellectual Property

Publications



- Data generated from testing of an Assay Developer's MCD test will be made available to the respective Assay Developer at the end of a given MCD Assay study.
- Developer will *not* publish any data before NCI investigators have published the data produced under any of the MCD Assay studies.
- Before any party intends to publicly disclose data produced under the MCD Assay studies, the non-disclosing party will have a chance to review such disclosure.
  - Example of timeline of review of public disclosures:
    - 3 days for abstracts and presentations
    - 7 days for press releases
    - 30 days for manuscripts*

**An extension may be provided upon written request as necessary to file or preserve any IP rights.*

Data Rights

Assay Developers

- Exclusive use of data produced under the agreements for:
  - Internal research purposes;
  - Development of the Developer's MCD test, including work with third party collaborators under obligations of confidentiality;
  - Regulatory filings; and
  - In support of existing patent filings.

NCI

- Use of data produced under the agreements for publication and internal research.

CSRN Sites (only applies to Vanguard and future CSRN studies)

- Use of data produced under the Vanguard and CSRN Studies for publication and internal research.
- Agree that Developers have the rights to use data as above.

Intellectual Property (IP) Rights

"Invention" means any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the U.S. Code…

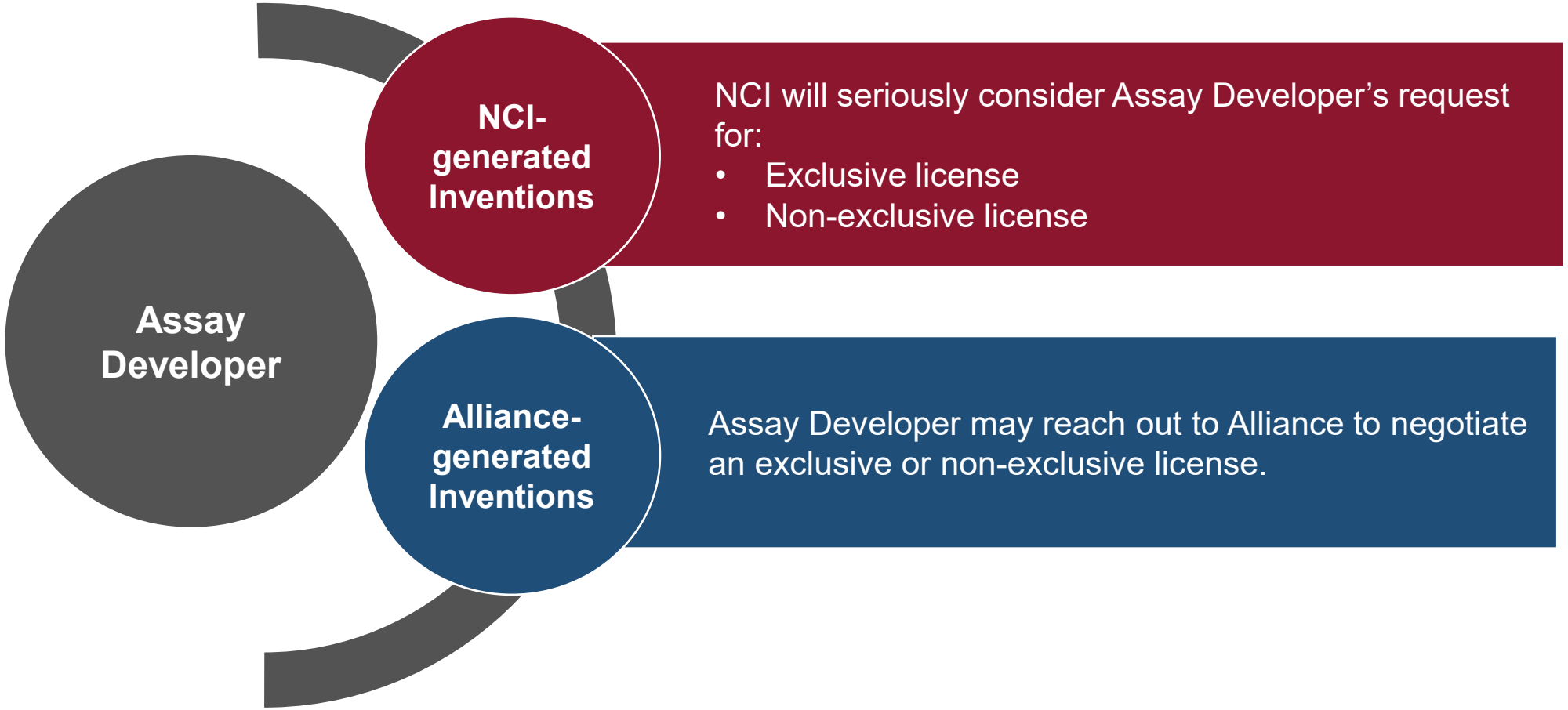
- Any invention generated during the conduct of work covered under an agreement will follow applicable laws, i.e., The Federal Technology Transfer Act (for NCI) and Bayh-Dole Act (for the CSRN sites).
- Inventorship will be determined by U.S. Patent law.
- The party that employs the inventor retains title to the inventions.
- If employees from more than one organization qualify as co-inventors, the employing organizations will jointly own the invention.
- Assay Developers will retain rights, title, and interest in any of their proprietary MCD tests and/or materials and data they contribute for any of the MCD Assay studies.

What happens if there is an Invention!??

Inventions: Performance Verification Process

- Conducted by Assay Developers using NCI-provided reference samples collected by Alliance
- Possibility of an Invention is rare to none
- NCI will notify Developer of any Inventions resulting from the verification of the respective Developer's MCD test
- Developer may reach out to NCI and/or Alliance for a license to such Invention

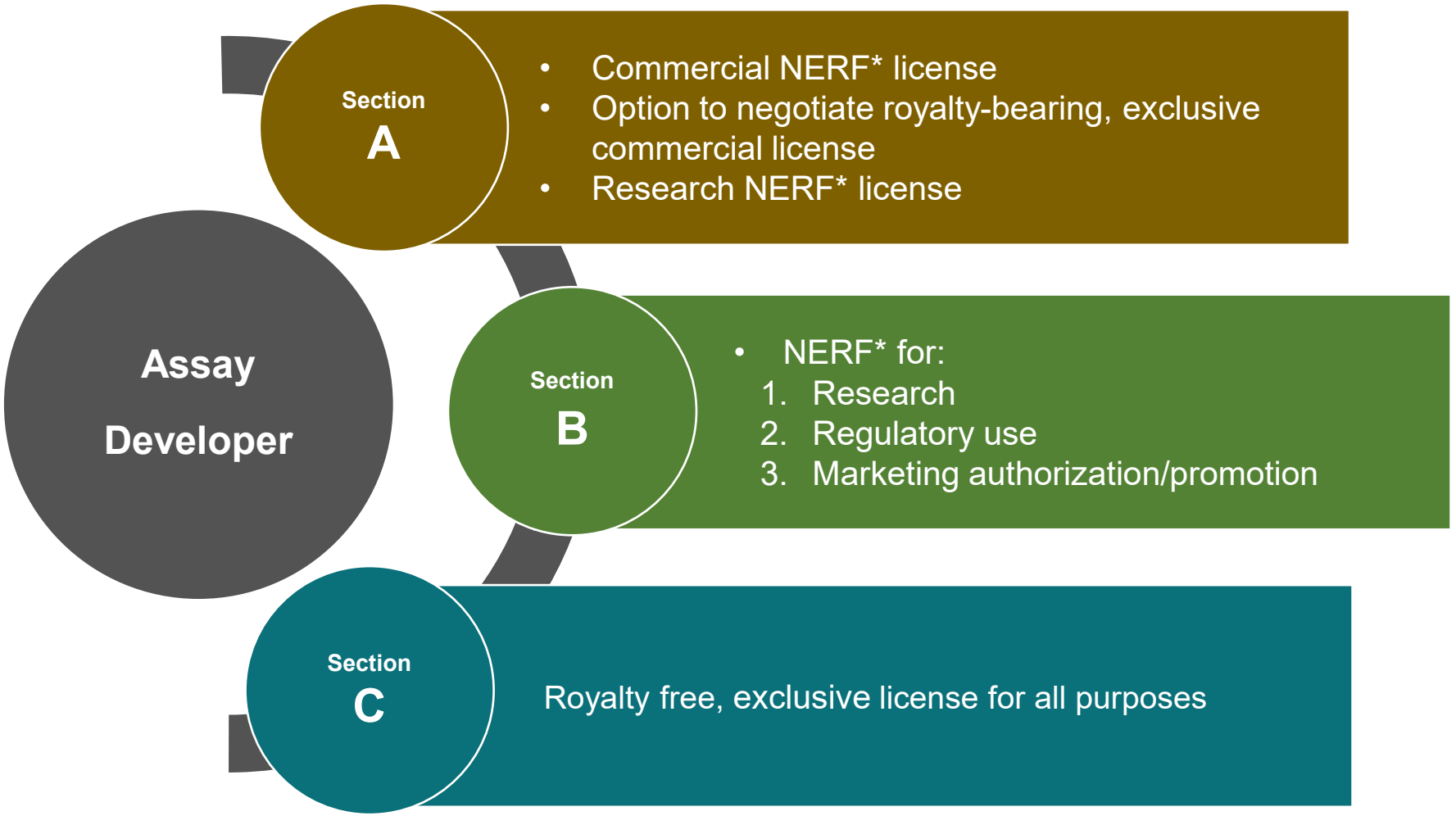
IP: Performance Verification Process (Stage 1)



Inventions: Vanguard & future CSRN Studies (Stages 2 & 3)

- Conducted by clinical sites under NCI's Cancer Screening Research Network (CSRN) using Assay Developer's MCD Test
- Possibility of an Inventions is very low to none
- NCI and the CSRN sites will notify Developer of any Inventions resulting from the study of the respective Developer's MCD Test
- Developer will receive an up-front IP licensing option (*CTEP IP option model*) from CSRN sites to these Inventions under its agreement with NCI

IP Option: Vanguard & future CSRN studies



***NERF =** Non-Exclusive, Royalty-Free License

Inventions

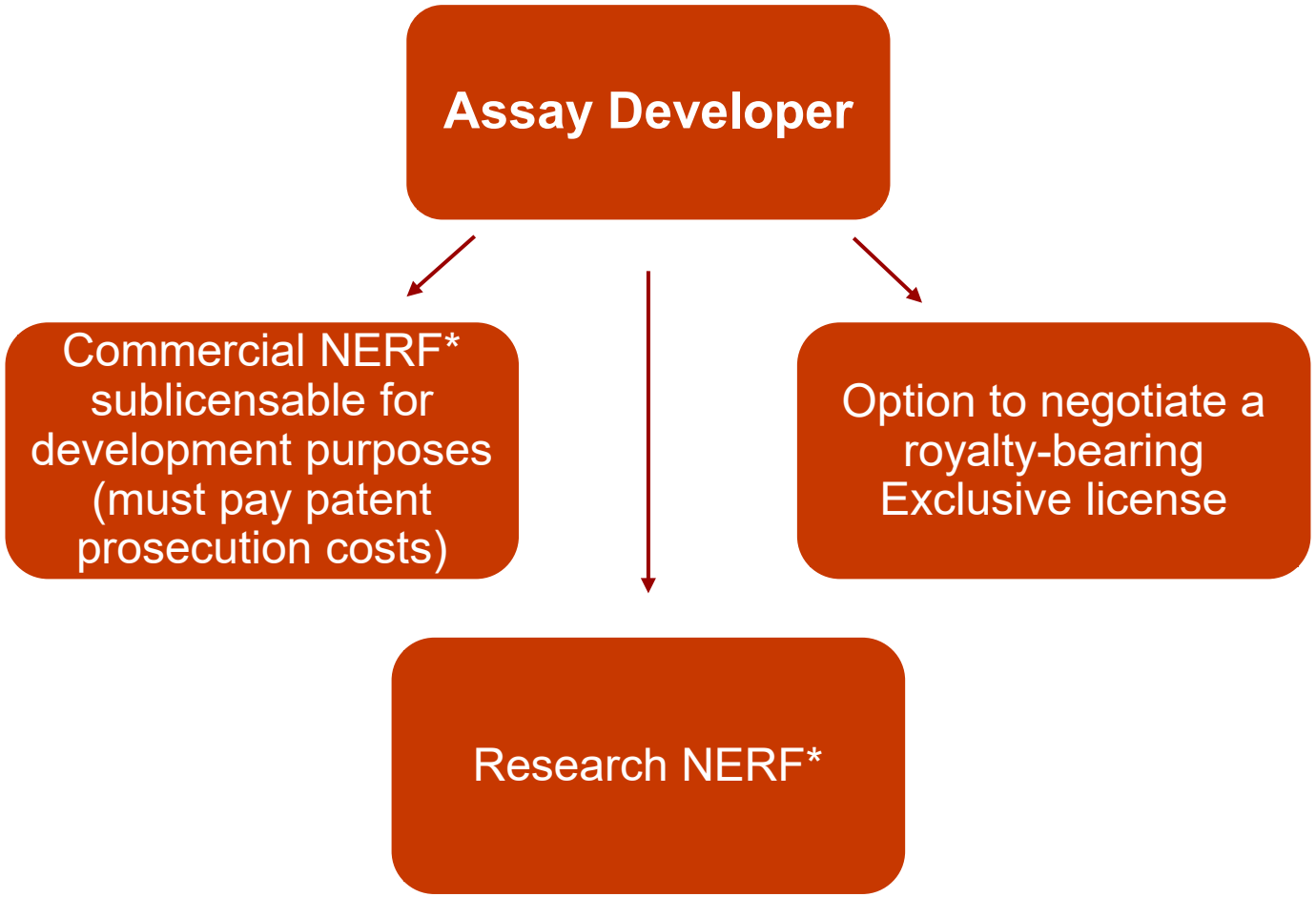
For Assay Developer

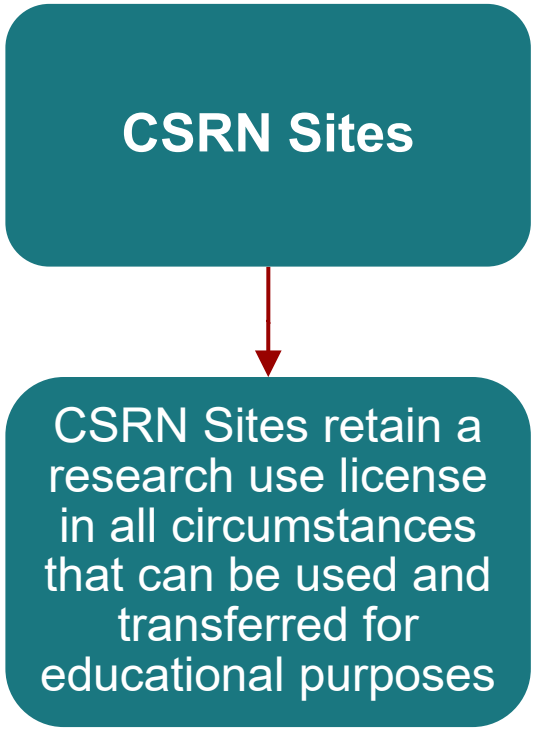
- **Section A =** claims the use and/or composition of Developer's MCD test.
- **Section B =** Not A, but invention discovered during the performance of non-clinical or clinical research involving Developer's MCD test, e.g. biomarkers or using data or materials from the study
- **Section C =** unauthorized use

For CSRN Sites

- **For all sections:** sites retain NERF for research and education purposes
- For Section C – Restriction on sublicensing NERF.

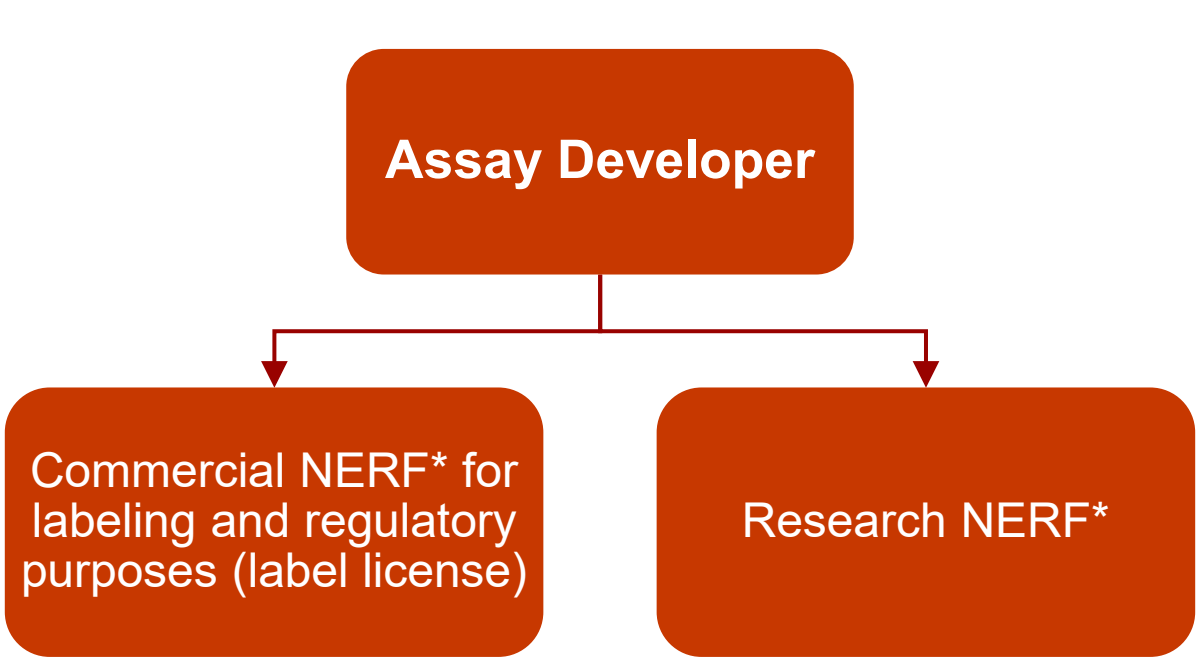
IP Option Rights: Section A Inventions
(Use or incorporate Developer's MCD Test)

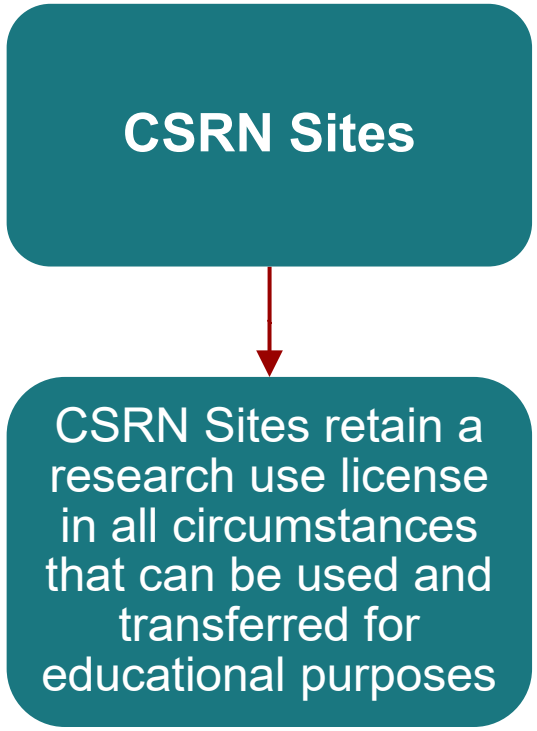




***NERF =** Non-Exclusive, Royalty-Free License

IP Option Rights: Section B Inventions
(Biomarkers and Assays)





***NERF =** Non-Exclusive, Royalty-Free License

IP Option Rights: Section C Inventions
(Unauthorized Use)

Assay Developer

↓

Royalty-free Exclusive license for all purposes

CSRN Sites

↓

CSRN Sites retain a research use license and ability to sublicense only for educational purposes in all circumstances

Key Points: Inventions from Performance Verification Process

1. NCI will notify Developer of any Inventions that may arise in connection with the work covered under the agreement with the Developer.
2. Developer may request an exclusive and/or a non-exclusive license to this Invention from NCI and Alliance.
3. NCI and Alliance will *seriously consider* Assay Developer's request for an exclusive and/or a non-exclusive license.

Key Points: Inventions from Vanguard & future CSRN studies

1. NCI and the CSRN site will notify the Developer of the Inventions.
2. Developer receives up-front licensing options under its agreement with NCI:
   - **From CSRN Site**:
     - Developer gets the first option to *negotiate* a royalty-bearing exclusive commercial license to Inventions that claim the Developer's MCD Test with the CSRN site.
     - Developer will *receive* a royalty-free non-exclusive commercial license.
     - Developer will *receive* a royalty-free non-exclusive research use license.
   - **From NCI:**
     - If NCI owns any rights in any such Inventions, NCI will *seriously consider* Developer's request for an exclusive and/or a non-exclusive license.

Takeaways

- Agreements will be established between NCI and each Assay Developer prior to its participation in any of the MCD Assay studies.
- Important Issues in Agreements:
  - Publications
  - Data Rights
  - Inventions & IP options
  - NCI or CSRN sites will not obtain any interest in a Developer's background IP, materials and/or data that they contribute to an MCD Assay study.

We are here to work with you and ensure your interests are protected

NIH NATIONAL CANCER INSTITUTE

NCI Virtual Workshop to Engage Multi-Cancer Detection (MCD) Assay Developers

Thank you!

Sidra Ahsan, Ph.D.
Jason Cristofaro, J.D., Ph.D.
Michael Pollack, Ph.D.