

## Examples of Co-Development Goals

### Example A). Early Testing of Collaborator's Agent

<b>Contributor Contribution</b>	<ul style="list-style-type: none"> <li>• Provides agent for testing</li> <li>• Files IND with the Food and Drug Administration</li> </ul>
<b>NIH Contribution</b>	<ul style="list-style-type: none"> <li>• Conducts preclinical research and Phase I studies in adult and/or pediatric patient populations at the NIH Clinical Center</li> <li>• Provides data in support of a new Investigational Drug (IND) application</li> </ul>
<b>Successful Outcome and/or Product</b>	<ul style="list-style-type: none"> <li>• Evaluation of a new agent including safety, tolerability, pharmacokinetics, immunogenicity, etc.</li> <li>• IND for agent</li> </ul>

### Example B). Research Collaborations for Evaluating Devices/Equipment

<b>Collaborator Contribution</b>	<ul style="list-style-type: none"> <li>• Places equipment in an NIH facility for testing by NIH scientists for a limited time</li> <li>• Offers onsite training sessions and technical support for NIH scientists interested in using the equipment</li> <li>• May provide equipment upgrades, accessories, reagents/disposables, and maintenance related to technology</li> </ul>
<b>NIH Contribution</b>	<ul style="list-style-type: none"> <li>• Conducts a variety of pilot studies to test the technology and compares results to the other methods</li> <li>• Assists in validating assays and methods</li> <li>• Provides data and other feedback for equipment and methods improvements</li> </ul>
<b>Successful Outcome and/or Product</b>	<ul style="list-style-type: none"> <li>• Improved product</li> </ul>

### Example C). Research Collaborations for Co-Development of New Antibodies

<b>Collaborator Contribution</b>	<ul style="list-style-type: none"> <li>• Designs and develops antibodies</li> <li>• Provides agreed upon quantity of product to NIH</li> </ul>
<b>NIH Contribution</b>	<ul style="list-style-type: none"> <li>• Chooses target proteins for antibody development</li> <li>• Validates using a wide variety of available cell systems</li> <li>• Provides validation data to company</li> </ul>
<b>Successful Outcome and/or Product</b>	<ul style="list-style-type: none"> <li>• Develops custom antibodies</li> <li>• Publish information about new antibodies</li> <li>• Create new antibody product</li> </ul>

### Example D). Clinical Testing of Agents Leading to New Therapeutics

**Collaborator Contribution**

- Provides or synthesizes the agent
- Conducts preclinical and clinical studies in collaboration with NIH and other institutions
- Works with NIH to develop data needed for FDA approval

**NIH Contribution**

- Provides or synthesizes the agent
- Conducts preclinical studies for the agent
- Develops or contributes to better formulation or alternative administration methods
- Conducts clinical trials through its network of clinical centers including NIH Clinical Center

**Successful Outcome and/or Product**

- FDA approval of agent
- Product on the market
- Other clinical trials for additional indications

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**Source**

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