

**EXAMPLES OF ACTIVITIES FOR BPN-BIOLOGICS PROJECTS**  
**(FOA 21-163 & FOA 21-233)**

*Please note the activities listed below are general examples, not all of them may need to be included. There may be some activities, not listed here, that will be required for a specific project.*

<b>DISCOVERY STAGE (UG3 or U44 Phase I)</b>	<b>DEVELOPMENT STAGE (UH3 or U44 Phase II)</b>
<p style="text-align: center;"><b>Lead Optimization Activities:</b></p> <ul style="list-style-type: none"> <li>• Lead candidate(s) optimization activities to down-select a final lead candidate</li> <li>• Small-scale manufacture (as needed)</li> <li>• <i>In vitro</i> characterization studies (as needed)</li> <li>• <i>In vivo</i> characterization (as needed)</li> <li>• Delivery routes optimization</li> <li>• Dose range determination</li> <li>• Pre-clinical and clinical bioassays validation</li> <li>• Preliminary PK/PD, toxicology studies</li> <li>• Final clinical lead candidate down-selection*</li> <li>• FDA meeting (e.g., INTERACT, pre-IND)</li> </ul>	<p style="text-align: center;"><b>cGMP Manufacturing Activities:</b></p> <ul style="list-style-type: none"> <li>• Process and analytical development</li> <li>• Small-scale GLP and/or clinical scale cGMP manufacturing</li> <li>• Fill-Finish, release testing, and product stability studies</li> </ul> <p style="text-align: center;"><b>Pre-Clinical IND enabling studies:</b></p> <ul style="list-style-type: none"> <li>• Confirmatory <i>in vivo</i> efficacy study using cGMP material (if required)</li> <li>• GLP PK/PD study using cGMP material in appropriate animal model(s)</li> <li>• Safety toxicology studies using cGMP material in appropriate animal model(s)</li> <li>• IND package preparation and submission**</li> <li>• Phase 1 clinical trial preparation (optional)</li> <li>• Phase 1 clinical trial initiation (optional)</li> </ul>

**\* Selection of a final clinical lead candidate is required in order to move on to the Development stage and is going to be a key milestone for all projects.**

**\*\*An IND submission is required for all proposals. It must be one of your Specific Aims for Development Stage.**