# Antibody Profile

The following table represents example categories to consider in describing your current results/status and desired results at the end funding period.

<table>
<thead>
<tr>
<th>Category</th>
<th>Parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Structure/Identity</strong></td>
<td>Class and sub-class&lt;br&gt;Light Chain Composition&lt;br&gt;Amino acid (AA) sequence&lt;br&gt;Carbohydrate content&lt;br&gt;AA-sequence confirmed by peptide mapping&lt;br&gt;3D structure&lt;br&gt;Epitope mapping</td>
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<tr>
<td><strong>In vitro activity</strong></td>
<td>Target binding: affinity/saturation&lt;br&gt;Bioactivity/potency&lt;br&gt;Stimulation of biological cascade&lt;br&gt;Tissue Selectivity&lt;br&gt;Selectivity/off-target effect to related target</td>
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<tr>
<td><strong>In vivo activity (such as target engagement/proximal downstream effect or efficacy) Indicate dose and route of administration</strong></td>
<td>Concentrations of testing agent in the serum and target tissue&lt;br&gt;Brain penetration&lt;br&gt;Serum half-life, AUC or other pharmacokinetic properties&lt;br&gt;Optimize Dose Selection and Schedule&lt;br&gt;ED50, Minimal effective dose, and Optimal effective dose&lt;br&gt;Treatment duration optimization&lt;br&gt;Treatment window optimization&lt;br&gt;Interactions with standard of care&lt;br&gt;Selectivity/off-target effect in vivo</td>
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<td><strong>Safety</strong></td>
<td>Tolerability&lt;br&gt;Antibodies to product&lt;br&gt;Tumorigenesis&lt;br&gt;Assess host immune response&lt;br&gt;Tissue Cross-Reactivity&lt;br&gt;Local reactogenicity&lt;br&gt;Cardiovascular, respiratory, renal and CNS safety pharmacology studies if any</td>
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<tr>
<td><strong>CMC</strong></td>
<td>Master/Working Virus Bank Status&lt;br&gt;Process development status&lt;br&gt;Analytical Assays for release testing with specifications&lt;br&gt;Scale-up feasibility&lt;br&gt;Formulation needs/development&lt;br&gt;Stability Analysis&lt;br&gt;Potency assays (in vitro/in vivo)&lt;br&gt;Delivery devices</td>
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<tr>
<td><strong>GLP analytical method development/validation</strong></td>
<td>Potency assays, assays for purity, pharmacokinetics and pharmacodynamics etc</td>
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<td><strong>Interactions with regulatory agencies</strong></td>
<td>Pre-IND</td>
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<tr>
<td><strong>Patent protection?</strong></td>
<td></td>
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</tbody>
</table>