Regulatory Assessment

1. What is the average length of time it takes for a developing drug to get to market?
   a. 5 years
   b. 7 years
   c. 12 years
   d. 15 years

2. IND stands for?
   a. Injection Narcotic Drug
   b. Introductory New Drug
   c. Investigational New Drug
   d. Industry Novelty Drug

3. What are the three phases of the regulatory process?
   a. Pre-clinical studies > clinical trials > FDA approval
   b. Pre-IND > IND > Post IND
   c. Pre-clinical studies > clinical trials > post-marketing
   d. Phase 1 > Phase 2 > Phase 3

4. Assays may need to be approved as a companion test in order for a new HIV “cure” drug to move to market.
   True
   False

5. Which if these factors would NOT be a factor in approving a product that offered a reduction in viral load?
   a. target population
   b. cost
   c. potential for retreatment
   d. safety

6. Before treatment interruptions in humans can occur researchers need know a biomarker that can predict success.
   True
   False
7. Of the responses listed only _________ is not an HIV cure-related risk consideration.
   a. Will the results be able to be applied to other populations?
   b. Will drug or trial procedures affect disease status or progression?
   c. Will the drug prevent reinfection?
   d. Will the trial increase partner risk of infection?

8. What is one purpose of a phase II IND trial?
   a. Verification of the drug’s safety and efficacy
   b. Determine how the drug is broken down by the body
   c. Compare different mechanisms to administer a drug
   d. Determine the best in country drug delivery system

9. The community can provide input into the regulatory process by all of these methods EXCEPT
   a. Advocates and trial sponsors
   b. Public meetings
   c. Twitter
   d. NDA committee meetings

10. Regulatory uncertainty regarding HIV cure research is largely associated with?
    a. Interagency policies
    b. Community uncertainty
    c. Scientific uncertainty
    d. There is no regulatory uncertainty
## Answer Key

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. C</td>
<td>Answer found on slide 3</td>
</tr>
<tr>
<td>2. C</td>
<td>Answer found on slide 4</td>
</tr>
<tr>
<td>3. C</td>
<td>Answer found on slide 3</td>
</tr>
<tr>
<td>4. TRUE</td>
<td>Answer found on slide 13</td>
</tr>
<tr>
<td>5. B</td>
<td>Answer found on slide 15</td>
</tr>
<tr>
<td>6. FALSE</td>
<td>Answer found on slide 13</td>
</tr>
<tr>
<td>7. C</td>
<td>Answer found on slide 13</td>
</tr>
<tr>
<td>8. A</td>
<td>Answer found on slide 6</td>
</tr>
<tr>
<td>9. C</td>
<td>Answer found on slide 16</td>
</tr>
<tr>
<td>10. C</td>
<td>Answer found on slide 13</td>
</tr>
</tbody>
</table>