

them with their preliminary window of consistency data package for the RP and the window of biosimilarity data package for its biosimilar), to avoid any surprises during the final biosimilarity assessment process.

In such an environment, the best we can do is try to convert the uncertainties we encountered into a situation of understanding the nature and extent of the risks we take, which we hope we can minimize, manage, and eventually remove through continual improvement of our scientific knowledge gained through the continual improvement of our analytical capabilities. By applying this mantra of maintaining our willingness to learn and apply our ever-increasing knowledge in the best way that we can, we can move forward to reap the opportunities and benefits of that increased but imperfect knowledge to improve the quality and longevity of our lives while minimizing the risks we unfortunately cannot totally avoid.

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