

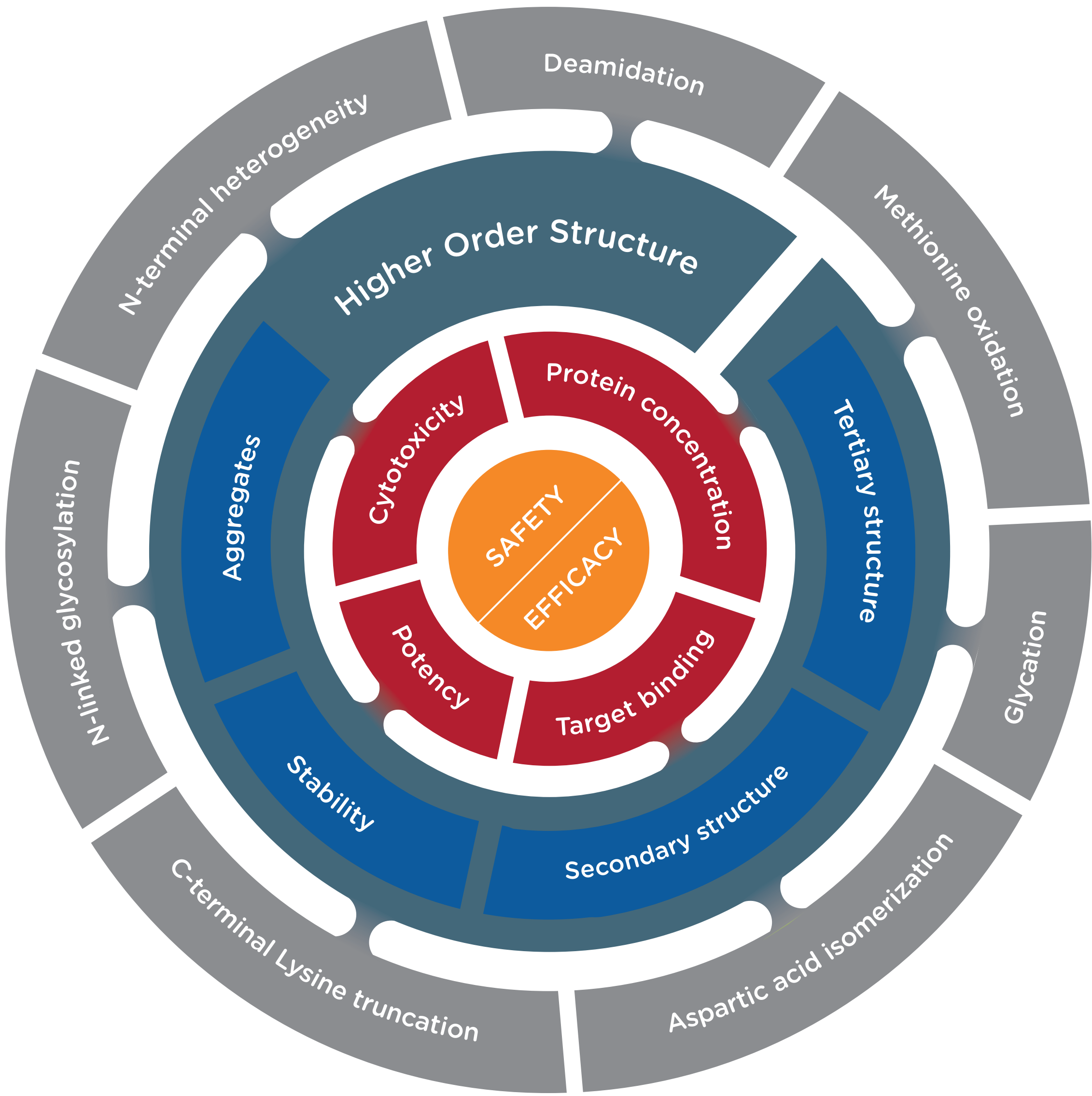
# TARGETING HOS IN BIOTHERAPEUTIC DEVELOPMENT

## 1 Highest risk CQAs impact directly on Safety and Efficacy

- Biopharma use a standardized science-/risk-based approach to ensure product **safety** and **efficacy**.
- **Critical quality attributes** (CQAs) are product characteristics that must be controlled to ensure safety and efficacy.

## 2 CQAs impact on Structure and Function

- The structure-function relationship is a central concept in protein science.
- The function of a protein is defined by its shape or structure.
- Risks associated with CQAs are best understood when impact on both structure and function is known.



## 3 HOS: CQA and measure of CQAs

- CQAs relating to **higher order structure** are important because **structural changes** lead to **functional changes**.
- **Higher order structure** is also important for assessing risk associated with other CQAs. Example: risk associated with asparagine deamidation is best understood by determining impact on both **structure** and **function**.

## 4 Regulatory agencies demand rigorous approaches

- Regulatory agencies require use of the **latest technology** and **orthogonal** approaches
- Biosimilar developers are expected to use appropriate **statistics** for objective decision making.

## CHIRASCAN

### Industry-ready systems built for HOS analysis

Orthogonal data: assess structure with far- and near-UV circular dichroism, absorbance and fluorescence

Automation: more walk-away time for increased productivity and flexible working

Faster and more robust decision making

Meet and exceed regulatory expectations

AppliedPhotophysics



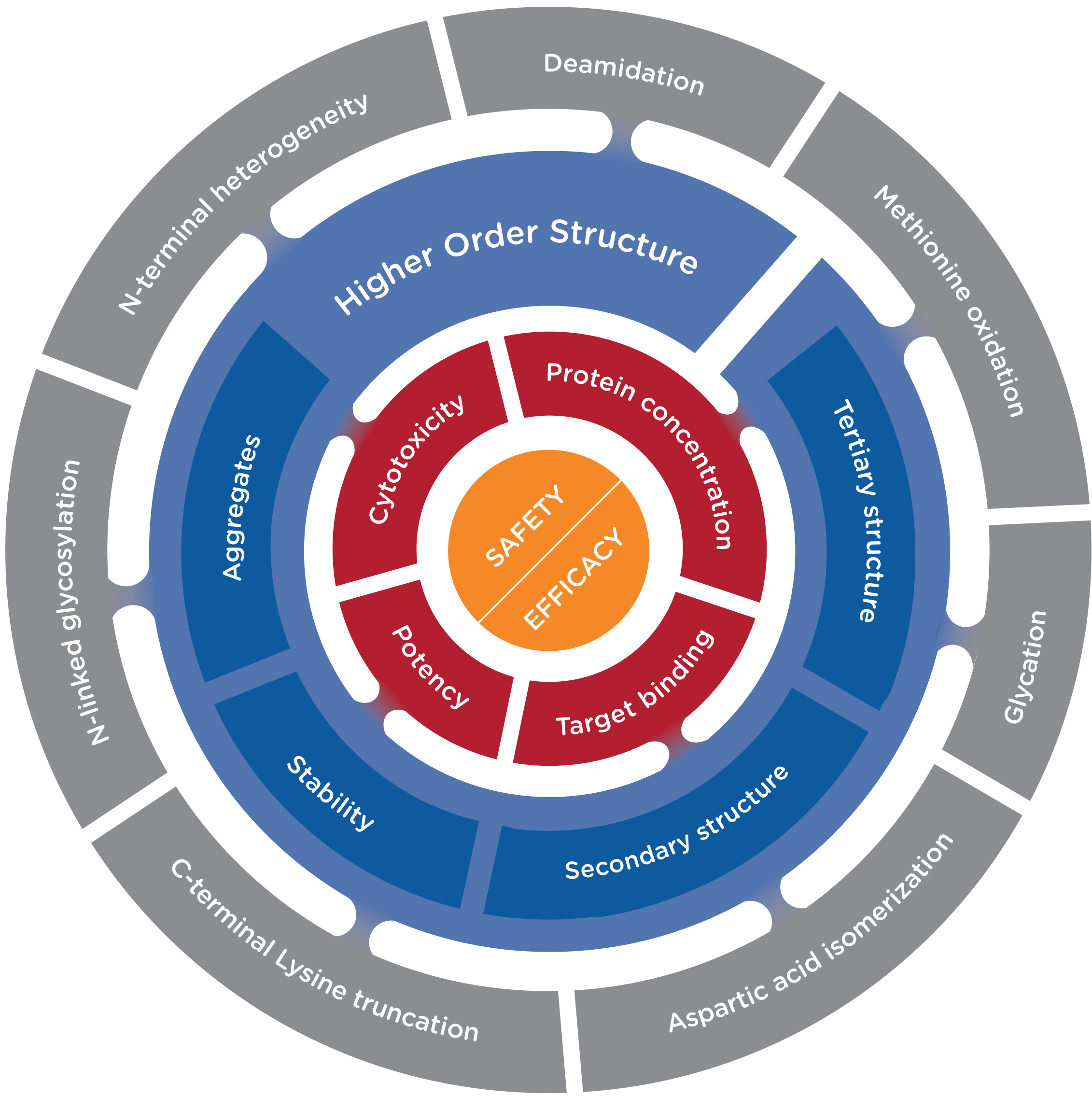
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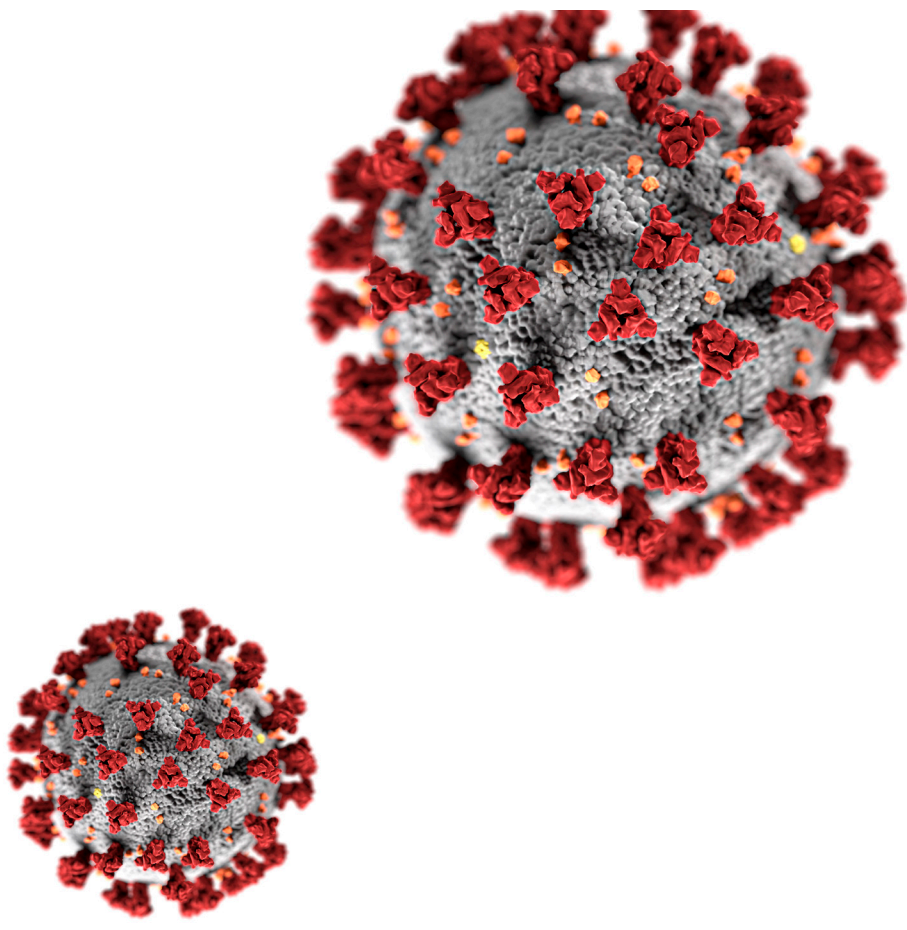


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