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## The 4<sup>th</sup> Glycan Forum in Berlin

### *Glycobiology – new developments for medicine, pharmaceutics and nutrition*

#### DEVELOPMENT OF A GLYCOSYLATED BIOSIMILAR PRODUCT: CASE STUDY

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Glycosylation plays a major role in the conformation and stability of proteins in the serum, protecting proteins from proteolysis, and improving protein solubility. The pharmaceutical industry marches towards biological drugs where most biopharmaceuticals contain glycosylation, which significantly affect their stability and activity. Glycosylation is highly sensitive to the process of protein-therapeutics manufacturing: the type of host cell, the particular clone chosen and the growth conditions, all affect the glycosylation of the products. Therefore, there is a growing need for characterization and monitoring of the glycan structure at all stages of discovery, development, and manufacturing of protein therapeutics. Currently used methods for glycoanalysis are lengthy, complex, typically requiring high levels of expertise, and are not applicable to samples at many stages of biopharmaceutical development.

Procognia has developed a lectin-array based method for rapid analysis of protein glycosylation. Use of lectins in glycoanalysis has been limited, mainly due to low specificity towards the various glycans found on glycoproteins. We have characterized these specificities using a large dataset of carefully chosen, well-characterized glycoproteins and extracted from these data mathematical functions capable of deconvoluting the large number of low-specificity signals obtained on the array to produce accurate, quantitative glycan profiles. This platform, the GlycoScope, enables high throughput glycoanalysis of the intact glycoprotein, at all stages of development and manufacturing of therapeutic proteins. Moreover, the GlycoScope is uniquely enabling for rapid selection of bio-generic copies of biological drugs, providing robust data package for biosimilar submission to health authorities. A case study for the application of a lectin-array based assay for glycoanalysis throughout product development stages of a therapeutic generic protein will be presented.