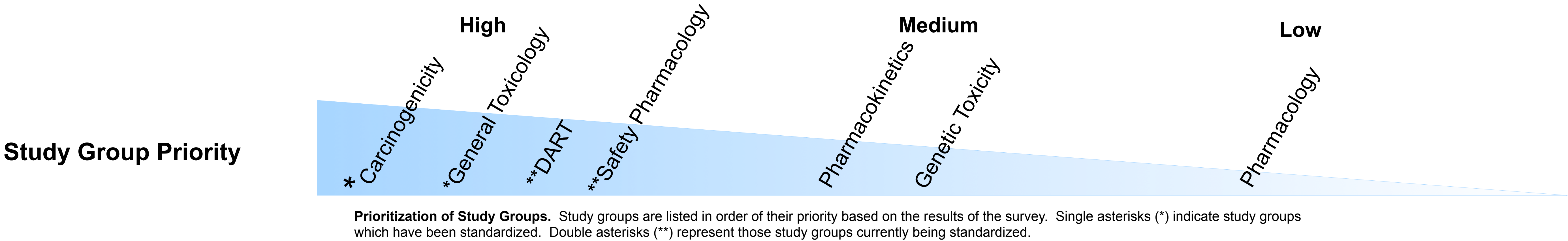


Priorities for a Nonclinical Standardization Roadmap

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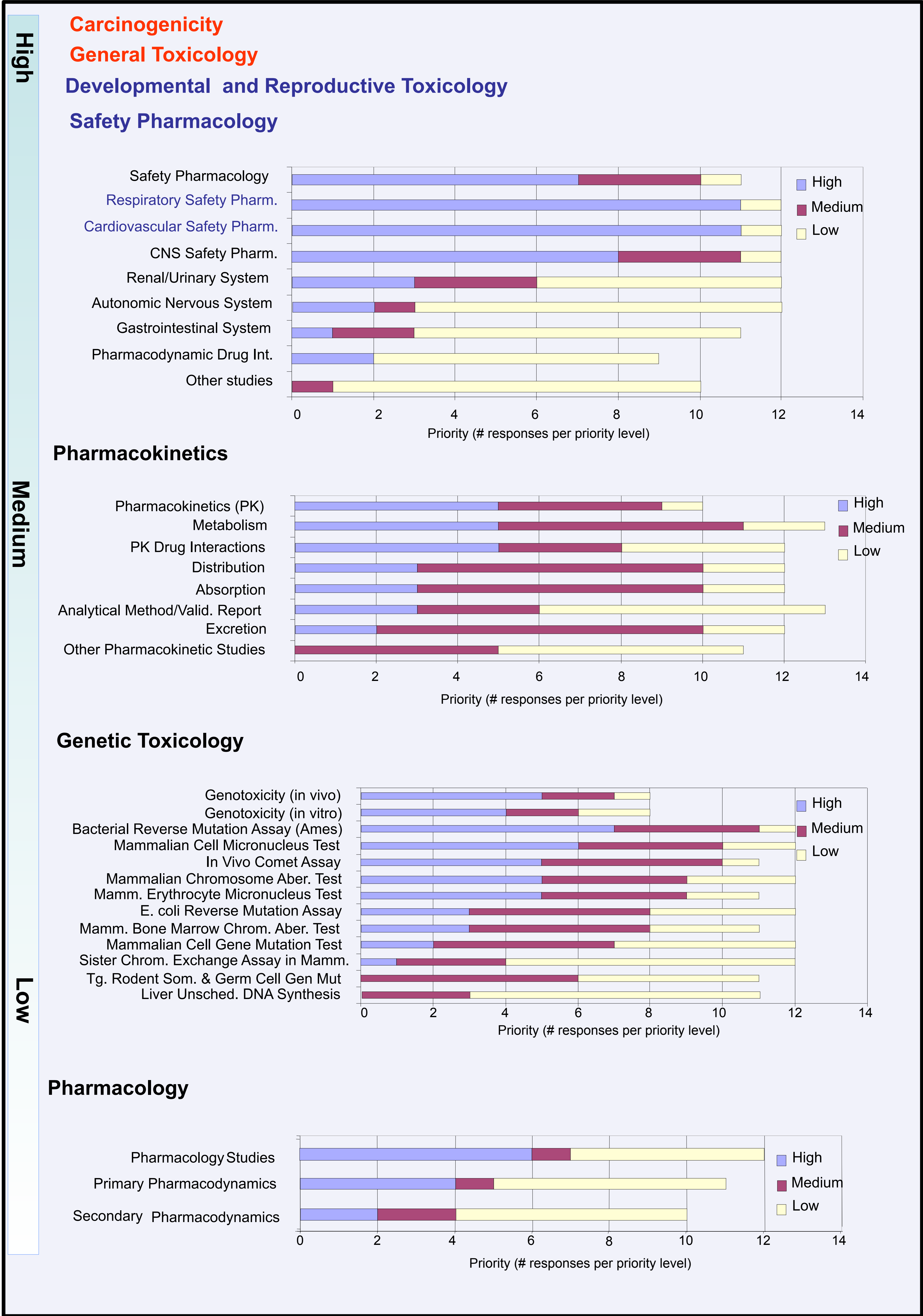
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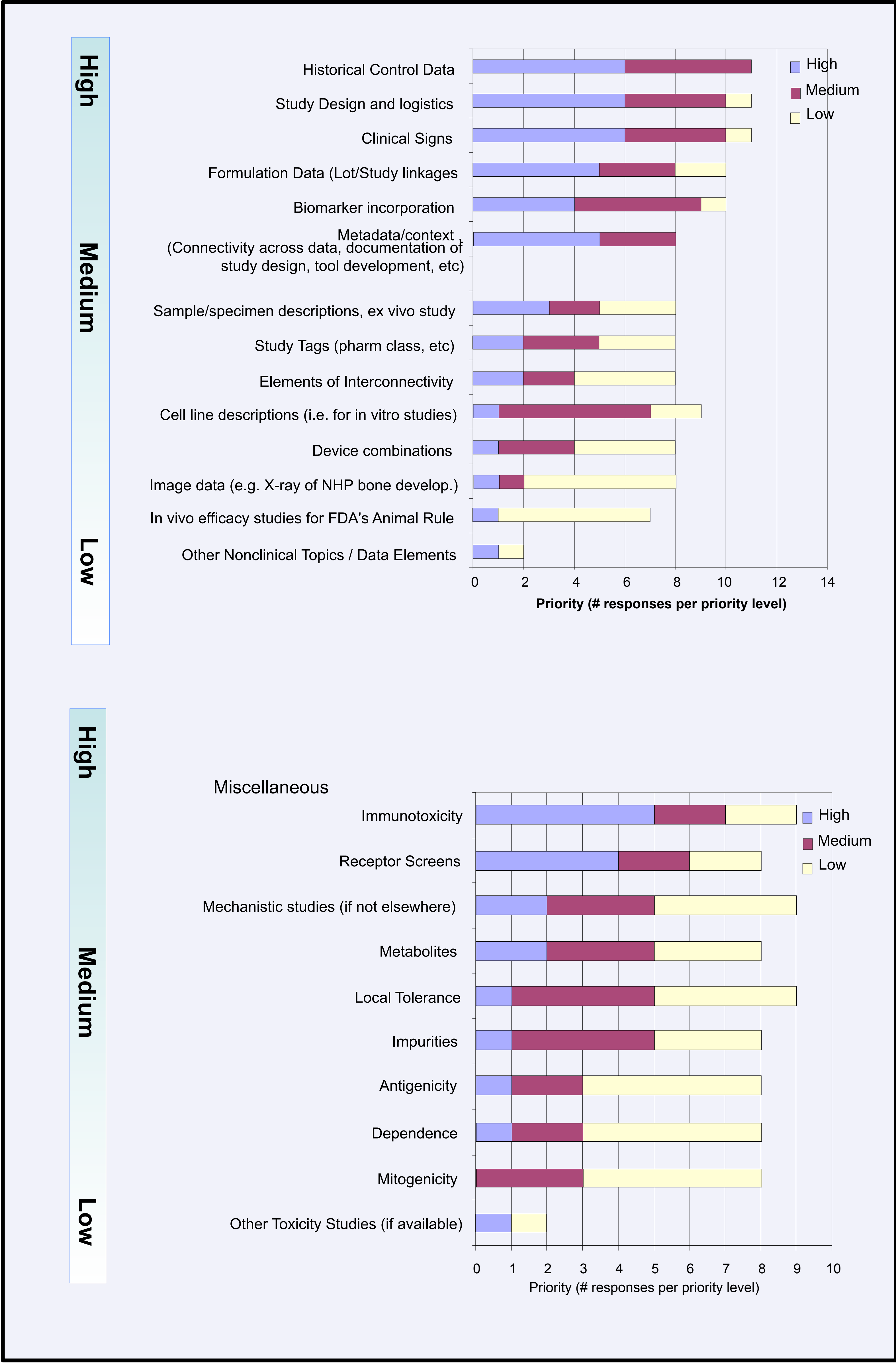
Introduction

The Standards Roadmap Team (a subset of the FDA / PhUSE Working Group 6) have forged a collaboration aimed at addressing common issues with data management, data standards, and standards implementation. To support this activity, the group created a survey for members of industry to further understand the priorities of the many stakeholders of nonclinical data. We asked them to consider the entire expanse of nonclinical studies listed for Module 4 of the eCTD. Responders rated the study types and data elements with a scale of high, medium, or low priority and also had the option of leaving it blank (indicating no particular preference). the respondents were provided with a text field where they could provide a rationale for their response. A spot to comment on rationale for the preference was provided, and responders were asked to indicate whether they were responding as an individual or on behalf of their organization. Respondents consisted of both companies/institutions (n=4) and individuals (n=11) throughout industry.

Study Type Priority



Data Elements Priority



Prioritization of Study Types. Individual study types were rated as high, medium, or low priority by survey respondents. **Red** Font indicates study groups that have been standardized. **Blue** font denotes study types that are currently being standardized.

Summary

The results of the survey indicated that carcinogenicity and general toxicology were the highest priority study groups. Next, developmental and reproductive toxicology (DART) and safety pharmacology were high priorities. DART studies (Segment I, II, III) were similar in their perceived priority, whereas safety pharmacology had both high and low priorities among their study types. Pharmacokinetics studies were medium priority along with genetic toxicology studies. Respondents differed on the utility of pharmacology studies, which received both high and low priority status. A prioritization of several data elements which can be applied across study types is also provided. The Roadmap team recognized value in keeping study types grouped since conventions of standardization may be applied to several study types within a study group. Data utility, accessibility, gaps and complexity along with metadata linkage, resources, timelines and technological advancements in collection and/or reporting systems should be considered and carefully integrated as the roadmap is created. As we continue our work, the Team will use the data collected and presented in this poster to suggest a roadmap for development of nonclinical standards.

Contact the Nonclinical Standardization Roadmap Working Group if you are interested in participating in this group at this link:
http://www.phusewiki.org/wiki/index.php?title=WG6_Nonclinical_-_Standardization_Roadmap or responding to the survey at this link:
http://www.phusewiki.org/wiki/index.php?title=File:Roadmap_Prioritization_PDF_V10.pdf.