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Current strategies in the non-clinical safety assessment of biologics: New targets, new molecules, new challenges

Frank R. Brennan, Laura Andrews, Antonio R. Arulanandam, Jorg Blumel, Jim Fikes, Christine Grimaldi, Janice Lansita, Lise I. Loberg, Tim MacLachlan, Mark Milton, Suezanne Parker, Jay Tibbitts, Jayanthi Wolf, Krishna P. Allamneni

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1 **Current Strategies in the Non-clinical Safety Assessment of Biologics: New Targets,**
2 **New Molecules, New Challenges**

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17 **Keywords:** adversity; biopharmaceuticals; bispecifics; cytokine release; emerging therapies;
18 gene and cell therapies; gene editing; immune-oncology; immunomodulation; microbiome;
19 minimum anticipated biological effect level (MABEL); monoclonal antibodies; no observed
20 adverse effect level (NOAEL); nonclinical safety; nonclinical species selection; oligonucleotide;
21 orphan drug; pharmacodynamics (PD); pharmacokinetics (PK); recombinant proteins.

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