Boris Gorovits

List of Publications by Year in descending order

60 papers	2,948 citations	212478 28 h-index	182931 54 g-index
70 all docs	70 docs citations	70 times ranked	2398 citing authors

#	Article	IF	Citations
1	When to Extend Monitoring of Anti-drug Antibodies for High-risk Biotherapeutics in Clinical Trials: an Opinion from the European Immunogenicity Platform. AAPS Journal, 2022, 24, 68.	2.2	1
2	2021 White Paper on Recent Issues in Bioanalysis: TAb/NAb, Viral Vector CDx, Shedding Assays; CRISPR/Cas9 & CAR-T Immunogenicity; PCR & Vaccine Assay Performance; ADA Assay Comparability & Cut Point AppropriatenessÂ(<u>Part 3</u>â€“ Recommendations on Gene Therapy,) Tj ETQq0 0 0 rgBT /Overlock	0.6	1
3	2020 White Paper on Recent Issues in Bioanalysis: BMV of Hybrid Assays, Acoustic MS, HRMS, Data Integrity, Endogenous Compounds, Microsampling and Microbiome (<u>Part 1</u> â€“ Recommendations) Tj ETQq1 1 0.784314 rgBT / Bioanalysis, 2021, 13, 203-220.	0.6	24
4	AAPS Perspective on the EURL Recommendation on the use of Non-Animal-Derived Antibodies. AAPS Journal, 2021, 23, 34.	2.2	3
5	2020 White Paper on Recent Issues in Bioanalysis: Vaccine Assay Validation, qPCR Assay Validation, QC for CAR-T Flow Cytometry, NAb Assay Harmonization and ELISpot Validation (<u>Part 3</u> â€“) Tj ETQq1 1 0.784314 rgBT /Overlock 415-463.	0.6	31
6	Application of blood microsampling in cynomolgus monkey and demonstration of equivalent monoclonal antibody PK parameters compared to conventional sampling. Pharmaceutical Research, 2021, 38, 819-830.	1.7	2
7	Feasibility of singlicate-based analysis in bridging ADA assay on Meso-Scale Discovery platform: comparison with duplicate analysis. Bioanalysis, 2021, 13, 1123-1134.	0.6	3
8	Evaluation of the Humoral Response to Adeno-Associated Virus-Based Gene Therapy Modalities Using Total Antibody Assays. AAPS Journal, 2021, 23, 108.	2.2	26
9	Complexity and diversity of bioanalytical support for gene therapy modalities. Bioanalysis, 2021, 13, 65-68.	0.6	2
10	Current Considerations on Characterization of Immune Response to Multi-Domain Biotherapeutics. BioDrugs, 2020, 34, 39-54.	2.2	15
11	Recommendations for the Development of Cell-Based Anti-Viral Vector Neutralizing Antibody Assays. AAPS Journal, 2020, 22, 24.	2.2	31
12	Strategies to develop highly drug-tolerant cell-based neutralizing antibody assay: neutralizing antidrug antibodies extraction and drug depletion. Bioanalysis, 2020, 12, 1279-1293.	0.6	3
13	Current Considerations for Immunoglobulin Isotype Characterization of Antibody Response against Biotherapeutics. AAPS Journal, 2020, 22, 144.	2.2	9
14	Development of a Highly Specific Anti-drug Antibody Assay in Support of a Nanoparticle-based Therapeutic. AAPS Journal, 2020, 22, 81.	2.2	0
15	Recommendations for singlet-based approach in ligand binding assays: an IQ Consortium perspective. Bioanalysis, 2020, 12, 823-834.	0.6	0
16	Bioanalytical assays in support of tanezumab developmental and reproductive toxicity studies: challenges and learnings. Bioanalysis, 2019, 11, 1205-1214.	0.6	0
17	Addressing soluble target interference in the development of a functional assay for the detection of neutralizing antibodies against a BCMA-CD3 bispecific antibody. Journal of Immunological Methods, 2019, 474, 112642.	0.6	6
18	Multiplexed immunoassay approach to characterize antidrug antibody like specific reactivity. Bioanalysis, 2019, 11, 703-712.	0.6	1

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19	Anti-drug Antibody Assay Validation: Improved Reporting of the Assay Selectivity via Simpler Positive Control Recovery Data Analysis. AAPS Journal, 2019, 21, 76.	2.2	1
20	Anti-drug Antibody Assay Conditions Significantly Impact Assay Screen and Confirmatory Cut-Points. AAPS Journal, 2019, 21, 71.	2.2	3
21	Immunogenicity of Chimeric Antigen Receptor T-Cell Therapeutics. BioDrugs, 2019, 33, 275-284.	2.2	52
22	Neutralizing Antibody Assay Development with High Drug and Target Tolerance to Support Clinical Development of an Anti-TFPI Therapeutic Monoclonal Antibody. AAPS Journal, 2019, 21, 46.	2.2	12
23	Bioanalysis of adeno-associated virus gene therapy therapeutics: regulatory expectations. Bioanalysis, 2019, 11, 2011-2024.	0.6	15
24	Approaches to Resolve False Reporting in Neutralizing Antibody Assays Caused by Reagent Leaching from Affinity Capture Elution Solid Phase. AAPS Journal, 2019, 21, 4.	2.2	5
25	Immunoassay methods used in clinical studies for the detection of anti-drug antibodies to adalimumab and infliximab. Clinical and Experimental Immunology, 2018, 192, 348-365.	1.1	57
26	Calibration Curves in Quantitative Ligand Binding Assays: Recommendations and Best Practices for Preparation, Design, and Editing of Calibration Curves. AAPS Journal, 2018, 20, 22.	2.2	40
27	A Simple Approach to Determine a Curve Fitting Model with a Correct Weighting Function for Calibration Curves in Quantitative Ligand Binding Assays. AAPS Journal, 2018, 20, 45.	2.2	17
28	2018 White Paper on Recent Issues in Bioanalysis: focus on flow cytometry, gene therapy, cut points and key clarifications on BAV (Part 3 â€“ LBA/cell-based assays: immunogenicity, biomarkers and PK) Tj ETQq0 0 0 rgBT /Overlock 10 Tf 5	0.6	44
29	Assessment of clinical immunogenicity of inotuzumab ozogamicin in patients with non-Hodgkin lymphoma and acute lymphoblastic leukemia. AAPS Open, 2018, 4, .	0.4	5
30	Preclinical Pharmacokinetics, Pharmacodynamics, Tissue Distribution, and Interspecies Scaling of Recombinant Human Coagulation Factor Xa I16L. Journal of Pharmaceutical Sciences, 2017, 106, 2136-2143.	1.6	9
31	Mitigation of Pre-existing Antibodies to a Biotherapeutic in Non-clinical Species When Establishing Anti-drug Antibody Assay Cutpoint. AAPS Journal, 2017, 19, 313-319.	2.2	9
32	Drug Target Interference in Immunogenicity Assays: Recommendations and Mitigation Strategies. AAPS Journal, 2017, 19, 1564-1575.	2.2	40
33	2017 White Paper on recent issues in bioanalysis: a global perspective on immunogenicity guidelines & biomarker assay performance (Part 3 â€“ LBA: immunogenicity, biomarkers and PK assays). Bioanalysis, 2017, 9, 1967-1996.	0.6	47
34	Recommendations for the Assessment and Management of Pre-existing Drug-Reactive Antibodies During Biotherapeutic Development. AAPS Journal, 2017, 19, 1576-1586.	2.2	17
35	Emerging Bioanalytical Methods for the Bioanalysis of Biotherapeutics. , 2017, , 180-197.		0
36	2016 White Paper on recent issues in bioanalysis: focus on biomarker assay validation (BAV): (Part 3 â€“) Tj ETQq0 0 0 rgBT /Overlock 1	0.6	49

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37	Pre-existing Antibody: Biotherapeutic Modality-Based Review. AAPS Journal, 2016, 18, 311-320.	2.2	58
38	2015 White Paper on recent issues in bioanalysis: focus on new technologies and biomarkers (Part 3 â€“) Tj ETQq0 0 0 rgBT /Overlock 1	0.6	64
39	Workshop Report: Crystal City Vâ€”Quantitative Bioanalytical Method Validation and Implementation: The 2013 Revised FDA Guidance. AAPS Journal, 2015, 17, 277-288.	2.2	109
40	Bioanalysis of antibodyâ€“drug conjugates. Bioanalysis, 2015, 7, 1559-1560.	0.6	8
41	Antibodyâ€“drug conjugates nonclinical support: from early to late nonclinical bioanalysis using ligand-binding assays. Bioanalysis, 2015, 7, 1605-1617.	0.6	26
42	2014 White Paper on recent issues in bioanalysis: a full immersion in bioanalysis (Part 2 â€“ hybrid) Tj ETQq0 0 0 rgBT /Overlock 10 Tf 5	0.6	45
43	PK of immunoconjugate anticancer agent CMD-193 in rats: ligand-binding assay approach to determinein vivoimmunoconjugate stability. Bioanalysis, 2014, 6, 21-32.	0.6	13
44	Protein-based matrix interferences in ligand-binding assays. Bioanalysis, 2014, 6, 1131-1140.	0.6	25
45	A White Paperâ€”Consensus and Recommendations of a Global Harmonization Team on Assessing the Impact of Immunogenicity on Pharmacokinetic Measurements. AAPS Journal, 2014, 16, 488-498.	2.2	55
46	Large Molecule Specific Assay Operation: Recommendation for Best Practices and Harmonization from the Global Bioanalysis Consortium Harmonization Team. AAPS Journal, 2014, 16, 83-88.	2.2	24
47	Recommendations for the characterization of immunogenicity response to multiple domain biotherapeutics. Journal of Immunological Methods, 2014, 408, 1-12.	0.6	56
48	Pre-Existing Biotherapeutic-Reactive Antibodies: Survey Results Within the American Association of Pharmaceutical Scientists. AAPS Journal, 2013, 15, 852-855.	2.2	35
49	Theoretical Considerations and Practical Approaches to Address the Effect of Anti-drug Antibody (ADA) on Quantification of Biotherapeutics in Circulation. AAPS Journal, 2013, 15, 646-658.	2.2	60
50	Considerations for the nonclinical safety evaluation of antibody drug conjugates for oncology. Regulatory Toxicology and Pharmacology, 2013, 67, 382-391.	1.3	36
51	Proposed mechanism of off-target toxicity for antibodyâ€“drug conjugates driven by mannose receptor uptake. Cancer Immunology, Immunotherapy, 2013, 62, 217-223.	2.0	74
52	Bioanalysis of antibodyâ€“drug conjugates: American Association of Pharmaceutical Scientists Antibodyâ€“Drug Conjugate Working Group position paper. Bioanalysis, 2013, 5, 997-1006.	0.6	144
53	Tissue bioanalysis of biotherapeutics and drug targets to support PK/PD. Bioanalysis, 2012, 4, 2589-2604.	0.6	34
54	Prevalence and Isotypic Complexity of the Anti-Chinese Hamster Ovary Host Cell Protein Antibodies in Normal Human Serum. AAPS Journal, 2010, 12, 98-106.	2.2	10

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55	Antidrug Antibody Assay Validation: Industry Survey Results. AAPS Journal, 2009, 11, 133-138.	2.2	26
56	Recommendations for the validation of immunoassays used for detection of host antibodies against biotechnology products. Journal of Pharmaceutical and Biomedical Analysis, 2008, 48, 1267-1281.	1.4	519
57	Recommendations on risk-based strategies for detection and characterization of antibodies against biotechnology products. Journal of Immunological Methods, 2008, 333, 1-9.	0.6	326
58	Antibody-targeted chemotherapy with CMC-544: a CD22-targeted immunoconjugate of calicheamicin for the treatment of B-lymphoid malignancies. Blood, 2004, 103, 1807-1814.	0.6	325
59	Pharmacokinetics of Gemtuzumab Ozogamicin as a Single-Agent Treatment of Pediatric Patients With Refractory or Relapsed Acute Myeloid Leukemia. Journal of Clinical Pharmacology, 2004, 44, 873-880.	1.0	54
60	High Hydrostatic Pressure Induces the Dissociation of cpn60 Tetradecamers and Reveals a Plasticity of the Monomers. Journal of Biological Chemistry, 1995, 270, 2061-2066.	1.6	51