

Author(s) Short	Year	Full Citation	Topic Area (If Specified)	Website/Link to Item
FDA	n/a	Report Title: Considerations for Discussion of a New Surrogate Endpoint(s) at a Type C PDUFA Meeting Request	Surrogate endpoints	<a href="https://www.fda.gov/media/115120/download">https://www.fda.gov/media/115120/download</a>
Sullivan	n/a	PowerPoint Title: Clinical Trial Endpoints	Primary, Surrogate, and Composite Endpoints	<a href="https://fda.report/media/91341/Presentation--Clinical-Trial-Endpoints--Eugene-J.-Sullivan--MD-FCCP.pdf">https://fda.report/media/91341/Presentation--Clinical-Trial-Endpoints--Eugene-J.-Sullivan--MD-FCCP.pdf</a>
Ahn & Jeung	2023	Ahn, C.; Jeung, E.-B. Endocrine-Disrupting Chemicals and Disease Endpoints. <i>Int. J. Mol. Sci.</i> 2023, 24, 5342. <a href="https://doi.org/10.3390/ijms24065342">https://doi.org/10.3390/ijms24065342</a>	endocrine system; disease endpoints associated with endocrine disruption	<a href="https://www.mdpi.com/1422-0067/24/6/5342">https://www.mdpi.com/1422-0067/24/6/5342</a>
Elliott	2023	Elliott, Michael R. "Surrogate Endpoints in Clinical Trials." <i>Annual Review of Statistics and Its Application</i> 2023 10:1, 75-96	Surrogate endpoints	<a href="https://www.annualreviews.org/doi/full/10.1146/annurev-statistics-032921-035359">https://www.annualreviews.org/doi/full/10.1146/annurev-statistics-032921-035359</a>
Holcomb et al	2021	Holcomb JB, Moore EE, Sperry JL, Jansen JO, Schreiber MA, Del Junco DJ, Spinella PC, Sauaia A, Brohi K, Bulger EM, Cap AP, Hess JR, Jenkins D, Lewis RJ, Neal MD, Newgard C, Pati S, Pusateri AE, Rizoli S, Russell RT, Shackelford SA, Stein DM, Steiner ME, Wang H, Ward KR, Young P. Evidence-Based and Clinically Relevant Outcomes for Hemorrhage Control Trauma Trials. <i>Ann Surg.</i> 2021 Mar 1;273(3):395-401. doi: 10.1097/SLA.0000000000004563. PMID: 33065652.	Optimal primary endpoints and clinical outcomes for bleeding patients	<a href="https://pubmed.ncbi.nlm.nih.gov/33065652/">https://pubmed.ncbi.nlm.nih.gov/33065652/</a>
Spinella et al	2021	Spinella PC, El Kassir N, Cap AP, Kindzelski AL, Almond CS, Barkun A, Gernsheimer TB, Goldstein JN, Holcomb JB, Iorio A, Jensen DM, Key NS, Levy JH, Mayer SA, Moore EE, Stanworth SJ, Lewis RJ, Steiner ME; Hemostasis Trials Outcomes Working Group. Recommended primary outcomes for clinical trials evaluating hemostatic blood products and agents in patients with bleeding: Proceedings of a National Heart Lung and Blood Institute and US Department of Defense Consensus Conference. <i>J Trauma Acute Care Surg.</i> 2021 Aug 1;91(2S Suppl 2):S19-S25. doi: 10.1097/TA.0000000000003300. PMID: 34039915; PMCID: PMC9032809.	Guidance for outcomes of hemostatic products	<a href="https://pubmed.ncbi.nlm.nih.gov/34039915/">https://pubmed.ncbi.nlm.nih.gov/34039915/</a>

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Martin et al	2020	Martin ND, Codner P, Greene W, Brasel K, Michetti C; AAST Critical Care Committee. Contemporary hemodynamic monitoring, fluid responsiveness, volume optimization, and endpoints of resuscitation: an AAST critical care committee clinical consensus. <i>Trauma Surg Acute Care Open</i> . 2020 Mar 10;5(1):e000411. doi: 10.1136/tsaco-2019-000411. PMID: 32201737; PMCID: PMC7066619.	Clinical guidance and endpoints of resuscitation	<a href="https://pubmed.ncbi.nlm.nih.gov/32201737/">https://pubmed.ncbi.nlm.nih.gov/32201737/</a>
McLeod et al	2019	McLeod C, Norman R, Litton E, Saville BR, Webb S, Snelling TL. Choosing primary endpoints for clinical trials of health care interventions. <i>Contemp Clin Trials Commun</i> . 2019 Nov 12;16:100486. doi: 10.1016/j.conctc.2019.100486. PMID: 31799474; PMCID: PMC6881606.	Endpoints in late phase trials	<a href="https://pubmed.ncbi.nlm.nih.gov/31799474/">https://pubmed.ncbi.nlm.nih.gov/31799474/</a>
Chang et al	2019	Chang R, Kerby JD, Kalkwarf KJ, Van Belle G, Fox EE, Cotton BA, Cohen MJ, Schreiber MA, Brasel K, Bulger EM, Inaba K, Rizoli S, Podbielski JM, Wade CE, Holcomb JB; PROPPR Study Group. Earlier time to hemostasis is associated with decreased mortality and rate of complications: Results from the Pragmatic Randomized Optimal Platelet and Plasma Ratio trial. <i>J Trauma Acute Care Surg</i> . 2019 Aug;87(2):342-349. doi: 10.1097/TA.0000000000002263. PMID: 31349348; PMCID: PMC6771437.	Time to hemostasis as an endpoint in trauma	<a href="https://pubmed.ncbi.nlm.nih.gov/31349348/">https://pubmed.ncbi.nlm.nih.gov/31349348/</a>
Butler et al	2019	Butler EK, Mills BM, Arbabi S, Bulger EM, Vavilala MS, Groner JJ, Stansbury LG, Hess JR, Rivara FP. Association of Blood Component Ratios With 24-Hour Mortality in Injured Children Receiving Massive Transfusion. <i>Crit Care Med</i> . 2019 Jul;47(7):975-983. doi: 10.1097/CCM.0000000000003708. PMID: 31205079; PMCID: PMC6581209.	Optimum blood product ratios	<a href="https://pubmed.ncbi.nlm.nih.gov/31205079/">https://pubmed.ncbi.nlm.nih.gov/31205079/</a>
Dadas et al	2018	Dadas A, Washington J, Diaz-Arrastia R, Janigro D. Biomarkers in traumatic brain injury (TBI): a review. <i>Neuropsychiatr Dis Treat</i> . 2018 Nov 8;14:2989-3000. doi: 10.2147/NDT.S125620. PMID: 30510421; PMCID: PMC6231511.	Fluid biomarkers; traumatic brain injury	<a href="https://pubmed.ncbi.nlm.nih.gov/30510421/">https://pubmed.ncbi.nlm.nih.gov/30510421/</a>

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Fox et al	2017	Fox EE, Holcomb JB, Wade CE, Bulger EM, Tilley BC; PROPPR Study Group. Earlier Endpoints are Required for Hemorrhagic Shock Trials Among Severely Injured Patients. Shock. 2017 May;47(5):567-573. doi: 10.1097/SHK.0000000000000788. PMID: 28207628; PMCID: PMC5392160.	Resuscitation/hemorrhage control intervention	<a href="https://pubmed.ncbi.nlm.nih.gov/28207628/">https://pubmed.ncbi.nlm.nih.gov/28207628/</a>
Williamson et al	2017	Williamson, P.R., Altman, D.G., Bagley, H. et al. The COMET Handbook: version 1.0. Trials 18 (Suppl 3), 280 (2017). <a href="https://doi.org/10.1186/s13063-017-1978-4">https://doi.org/10.1186/s13063-017-1978-4</a>	4 step process to develop a core outcome set	<a href="https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-017-1978-4#citeas">https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-017-1978-4#citeas</a>
Arakaki et al	2017	Arakaki LSL, Bulger EM, Ciesielski WA, Carlbom DJ, Fisk DM, Sheehan KL, Asplund KM, Schenkman KA. Muscle Oxygenation as an Early Predictor of Shock Severity in Trauma Patients. Shock. 2017 May;47(5):599-605. doi: 10.1097/SHK.0000000000000787. PMID: 27820776; PMCID: PMC5392146.	Noninvasive muscle oxygenation (MOx) measurement for the identification of shock severity	<a href="https://pubmed.ncbi.nlm.nih.gov/27820776/">https://pubmed.ncbi.nlm.nih.gov/27820776/</a>
Bulger et al	2017	Bulger EM, May A, Dankner W, Maislin G, Robinson B, Shirvan A. Validation of a clinical trial composite endpoint for patients with necrotizing soft tissue infections. J Trauma Acute Care Surg. 2017 Oct;83(4):622-627. doi: 10.1097/TA.0000000000001564. PMID: 28538644.	Necrotizing soft tissue infections	<a href="https://pubmed.ncbi.nlm.nih.gov/28538644/">https://pubmed.ncbi.nlm.nih.gov/28538644/</a>
Galvagno et al	2017	Galvagno SM Jr, Fox EE, Appana SN, Baraniuk S, Bosarge PL, Bulger EM, Callcut RA, Cotton BA, Goodman M, Inaba K, O'Keeffe T, Schreiber MA, Wade CE, Scalea TM, Holcomb JB, Stein DM; PROPPR Study Group. Outcomes after concomitant traumatic brain injury and hemorrhagic shock: A secondary analysis from the Pragmatic, Randomized Optimal Platelets and Plasma Ratios trial. J Trauma Acute Care Surg. 2017 Oct;83(4):668-674. doi: 10.1097/TA.0000000000001584. Epub 2017 Jun 6. PMID: 28930959; PMCID: PMC5718977.	Clinical Outcomes after TBI and hemorrhagic shock	<a href="https://pubmed.ncbi.nlm.nih.gov/28930959/">https://pubmed.ncbi.nlm.nih.gov/28930959/</a>

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Heaney et al	2017	Heaney JB, Schroll R, Turney J, Stuke L, Marr AB, Greiffenstein P, Robledo R, Theriot A, Duchesne J, Hunt J. Implications of the Trauma Quality Improvement Project inclusion of nonsurvivable injuries in performance benchmarking. J Trauma Acute Care Surg. 2017 Oct;83(4):617-621. doi: 10.1097/TA.0000000000001577. PMID: 28930956.	Biased outcomes: inclusion of patients with nonsurvivable injuries biases outcomes	<a href="https://pubmed.ncbi.nlm.nih.gov/28930956/">https://pubmed.ncbi.nlm.nih.gov/28930956/</a>
FDA-NIH Biomarker Working Group.	2016	FDA-NIH Biomarker Working Group. BEST (Biomarkers, Endpoints, and other Tools) Resource [Internet]. Silver Spring (MD): Food and Drug Administration (US); 2016-. Glossary. 2016 Jan 28 [Updated 2018 May 2]. Co-published by National Institutes of Health (US), Bethesda (MD).	Definitions and key terms	<a href="https://www.ncbi.nlm.nih.gov/books/NBK326791/">https://www.ncbi.nlm.nih.gov/books/NBK326791/</a>
Champion et al	2016	Champion HR, Lombardo LV, Wade CE, Kalin EJ, Lawnick MM, Holcomb JB. Time and place of death from automobile crashes: Research endpoint implications. J Trauma Acute Care Surg. 2016 Sep;81(3):420-6. doi: 10.1097/TA.0000000000001124. PMID: 27257691.	prehospital & in-hospital motor vehicle crash-related deaths; endpoints	<a href="https://pubmed.ncbi.nlm.nih.gov/27257691/">https://pubmed.ncbi.nlm.nih.gov/27257691/</a>
Alawadi et al	2015	Alawadi ZM, LeFebvre E, Fox EE, Del Junco DJ, Cotton BA, Wade CE, Holcomb JB. Alternative end points for trauma studies: A survey of academic trauma surgeons. Surgery. 2015 Nov;158(5):1291-6. doi: 10.1016/j.surg.2015.03.030. Epub 2015 May 7. PMID: 25958063.	Endpoints for Trauma Studies	<a href="https://pubmed.ncbi.nlm.nih.gov/25958063/">https://pubmed.ncbi.nlm.nih.gov/25958063/</a>
Savage et al	2015	Savage SA, Sumislawski JJ, Zarzaur BL, Dutton WP, Croce MA, Fabian TC. The new metric to define large-volume hemorrhage: results of a prospective study of the critical administration threshold. J Trauma Acute Care Surg. 2015 Feb;78(2):224-9; discussion 229-30. doi: 10.1097/TA.0000000000000502. PMID: 25757105.	Transfusion: massive transfusion (MT) vs. critical administration threshold (CAT)	<a href="https://pubmed.ncbi.nlm.nih.gov/25757105/">https://pubmed.ncbi.nlm.nih.gov/25757105/</a>

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Rainer et al	2014	Rainer TH, Yeung JH, Cheung SK, Yuen YK, Poon WS, Ho HF, Kam CW, Cattermole GN, Chang A, So FL, Graham CA. Assessment of quality of life and functional outcome in patients sustaining moderate and major trauma: a multicentre, prospective cohort study. <i>Injury</i> . 2014 May;45(5):902-9. doi: 10.1016/j.injury.2013.11.006. Epub 2013 Nov 21. PMID: 24314871.	Quality of life and functional outcome	<a href="https://pubmed.ncbi.nlm.nih.gov/24314871/">https://pubmed.ncbi.nlm.nih.gov/24314871/</a>
Holcomb et al	2011	Holcomb JB, Weiskopf R, Champion H, Gould SA, Sauer RM, Brasel K, Bochicchio G, Bulger E, Cotton BA, Davis D, Dutton R, Hauser CJ, Hess JR, Hides GA, Knudson P, MacKenzie E, McGinnis RL, Michalek J, Moore FA, Omert L, Pollock BH, Tortella B, Sugarman J, Schreiber MA, Wade CE. Challenges to effective research in acute trauma resuscitation: consent and endpoints. <i>Shock</i> . 2011 Feb;35(2):107-13. doi: 10.1097/SHK.0b013e3181f7fd01. PMID: 20926987.	Resuscitation for acute trauma injury with hemorrhagic shock	<a href="https://journals.lww.com/shockjournal/fulltext/2011/02000/challenges_to_effective_research_in_acute_trauma.2.aspx">https://journals.lww.com/shockjournal/fulltext/2011/02000/challenges_to_effective_research_in_acute_trauma.2.aspx</a>
Sinha et al	2011	Sinha IP, Smyth RL, Williamson PR. Using the Delphi technique to determine which outcomes to measure in clinical trials: recommendations for the future based on a systematic review of existing studies. <i>PLoS Med</i> . 2011 Jan 25;8(1):e1000393. doi: 10.1371/journal.pmed.1000393. PMID: 21283604; PMCID: PMC3026691.	Core outcomes to measure	<a href="https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1000393">https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1000393</a>
Wade & Holcomb	2005	Wade CE, Holcomb JB. Endpoints in clinical trials of fluid resuscitation of patients with traumatic injuries. <i>Transfusion</i> . 2005 Jul;45(1 Suppl):4S-8S. doi: 10.1111/j.0041-1132.2005.00156.x. PMID: 15989685.	Resuscitation	<a href="https://pubmed.ncbi.nlm.nih.gov/15989685/">https://pubmed.ncbi.nlm.nih.gov/15989685/</a>
Tisherman et al	2004	Tisherman SA, Barie P, Bokhari F, Bonadies J, Daley B, Diebel L, Eachempati SR, Kurek S, Luchette F, Carlos Puyana J, Schreiber M, Simon R. Clinical practice guideline: endpoints of resuscitation. <i>J Trauma</i> . 2004 Oct;57(4):898-912. doi: 10.1097/01.ta.0000133577.25793.e5. PMID: 15514553.	Resuscitation	<a href="https://pubmed.ncbi.nlm.nih.gov/15514553/">https://pubmed.ncbi.nlm.nih.gov/15514553/</a>