



Spotlight: CTN0098 Exemplar Hospital Initiation Trial to Enhance Treatment Engagement (EXHIT ENTRE)

National Status: The 0098A protocol has been submitted to the central IRB and is under review and pending IRB approval. The national training occurred on April 7 and April 9, and all study sites participated. Staff at each site are now completing remaining self-paced trainings, as well as post-training quizzes to verify competency. Site initiation visits are expected to occur in May. If all goes as planned with IRB review and approval, as well as site initiation visits, 0098A hopes to begin recruiting and enrolling patients in May or June.

***Local site status and staff:**

- Boston University: Dr. Zoe Weinstein is Site PI. Drs. Alexander Walley and Alyssa Peterkin are Co-Investigators. Kara Magane is the Project Manager, and Sarah Fielman is the Research Assistant. BU is preparing for study launch (purchasing study supplies, developing local SOPs, etc).
- Yale: Dr. E. Jennifer Edelman is Site PI. Drs. Shawn Cohen and Melissa Weimer are Co-Investigators. Renee Capasso and Liz Perrotti are Research Coordinators. Joanne Corvino is the Regulatory Specialist. Yale is preparing for study launch.
- MGH: Dr. Sarah Wakeman is Site PI & Medical Clinician for 98A at the MGH site. Dr. Gene Lambert is the Co-Investigator & Medical Clinician. Samantha Sawyer is the Project Manager, and is responsible for Regulatory Affairs & Quality Assurance, and Giovanie Yacorps is the Research Coordinator. MGH is preparing for study launch.

National Status: The 0098B protocol was submitted to central IRB in February and was approved by the IRB in early March. The Lead Team is now planning the national training, which is anticipated to occur in late May or early June. The 4 participating Hub/sites have started to reach out to potentially eligible community hospitals in their states to recruit them to participate in the 0098B study.

***Local site status and staff:**

- Boston University: Dr. Zoe Weinstein is Site PI. Drs. Alexander Walley, Alyssa Peterkin, and Amy Fitzpatrick are Co-Investigators. Kara Magane is the Project Manager, and Sarah Fielman is the Research Assistant.

CTN-0098A Yale

- Renee Capasso, Research Coordinator
- Shawn Cohen, MD, Co-I
- Cynthia Morgan, NE Node
- E. Jennifer Edelman, MD, MHS, Site-PI
- Joanne Corvino, Regulatory
- Liz Perrotti, Research Coordinator
- Melissa Weimer, DO, Co-I

CTN-0098A/B BU

- Alexander Walley, MD, MSc, Co-I, *0098A/0098B
- Zoe Weinstein MD, MS, Site PI, 0098A/0098B
- Kara Magane, Project Manager, 0098A/0098B
- Alyssa Peterkin MD, Medical Clinician/Co-I, 0098A/0098B
- Sarah Fielman, Research Assistant, 0098A/0098B
- Richard Saitz MD, MPH, Co-Lead Investigator and Site Co-I, 0098A/0098B
- Amy Fitzpatrick, MD, Co-I, 0098B

CTN-0098A MGH

- Sarah Wakeman, Site PI & Medical Clinician
- Gene Lambert, Co-I & Medical Clinician
- Giovanie Yacorps, Research Coordinator
- Samantha Sawyer, Project Manager, Regulatory Affairs, & Quality Assurance

Awards



Shelly F. Greenfield, MD, MPH (McLean Hospital/Harvard Medical School) from the New England Consortium Node was the featured presenter at the annual Harvard Medical School (HMS) Hollis L. Albright, MD '31 Symposium on Wednesday March 3, 2021. Dr. Greenfield's talk, "Women and Addiction: From Science to Policy" was a presentation of the science underpinning a gender-specific approach to optimizing addiction prevention and recovery for women. [Hollis L. Albright, MD '31 Symposium | Harvard Medical Alumni Association](#)

Gail D'Onofrio, MD, MS, FACEM, FASAM (Yale School of Medicine), one of the New England Consortium Node PIs, is receiving the R. Brinkley Smithers Distinguished Scientist Award. The Award recognizes and honors an individual who has made highly meritorious contributions in advancing the scientific understanding of addiction, its *prevention and treatment*. <https://www.asam.org/membership/asam-award-programs/awards-recognition>

Richard Saitz, MD, MPH, FACP, DFASAM (Boston University) is receiving the ASAM Educator of the Year Award. The ASAM Educator of the Year Award recognizes and honors an educator who has made outstanding contributions to ASAM's addiction medicine education. <https://www.asam.org/membership/asam-award-programs/awards-recognition>

Kathryn Hawk, M.D., M.H.S. (Yale University Department of Emergency Medicine) is receiving CPDD's F.O.R.C.E. Award (Female Opioid-addiction Research and Clinical Experts), given to female early career investigators conducting research on opioids. <https://cpdd.org/awards/travel-awards/travel-awards-winners/>

Kathryn Hawk, M.D., M.H.S. is receiving the Academy for Women in Academic Emergency Medicine (AWAEM) Early Career Research Award, to be presented at the Society for Academic Emergency Medicine National Conference May 12-15th.

Studies about to START!

CTN-0098A/B Exemplar Hospital Initiation Trial to Enhance Treatment Engagement (EXHIT ENTRE)
Sites: A: BU, MGH, YNH & B: BU

CTN-0100 Optimizing Retention, Duration & Discontinuation Strategies for OUD Pharmacotherapy (RDD)
Sites: Liberation (Bridgeport, CT), SSTAR (Fall River, MA), Square Medical (Watertown, MA)

Site Selection Process CCTN-0112 Optimal Policies to Improve Methadone Maintenance Adherence Longterm (OPTIMMAL): Root Center, Hartford, CT & APT Foundation, New Haven, CT submitted

Presentations

Ayana Jordan: Presented at the CTN Workshop: Reducing Disparities in SUD Treatment Among African Americans, March 3-4, 2021.

Shelly Greenfield: Gender Differences in Substance Use Disorders: Implications for Women's Addiction Treatment, Cincinnati Women's Club Endowed Lectureship, University of Cincinnati School of Medicine, Grand Rounds Presentation, March 31, 2021.

Sharon Levy: Presenting review of virtual recruitment strategies for adolescents and compare the yield of different methods at:

- Society on Clinical Research Associates, May
- CTN Steering Committee Meeting, April 28

Gail D'Onofrio: Presented the opening Plenary Session at ASAM (April 22-24); ED-initiated Buprenorphine for Opioid Use Disorder: Should it be a choice?

Gail D'Onofrio: PCSS Webinar April 13, "Treatment of Opioid Use Disorder in the ED", sponsored by the APA and AAAP.

David Fiellin, Jeanette Tetrault, Jared Klein, Sarah Wakeman, David Liu, Jen Edelman: Presented a workshop at the Society for General Internal Medicine, related to CTN0069, entitled, "Emergency Department-Initiated Buprenorphine: An Opportunity for Generalists to Collaborate with ED's to Address the Opioid Crisis" on 4/20/21 from 12:20-1:50.

Papers

Barbosa-Leiker C, Campbell ANC, McHugh RK, Guille C, Greenfield SF. **Opioid Use Disorder in Women and the Implications for Treatment.** *Psych Res Clin Practice*. October 13, 2020.
<https://onlinelibrary.wiley.com/doi/10.1176/appi.prcp.20190051>

Boudreau DM, Lapham G, Johnson EA, Bobb JF, Matthews AG, McCormack J, Liu D, Campbell CI, Rossom RC, Binswanger IA, Yarborough BJ, Arnsten JH, Cunningham CO, Glass JE, Murphy MT, Zare M, Hechter RC, Ahmedani B, Braciszewski JM, Horigian VE, Szapocznik J, **Samet JH**, Saxon AJ, Schwartz RP, Bradley KA. **Documented opioid use disorder and its treatment in primary care patients across six U.S. health systems.** *J Substance Abuse Treat*. 2020; 112:41-48.

Campbell CI, Saxon AJ, Boudreau D, Wartko PD, Bobb JF, Lee AK, Matthew AG, McCormack J, Liu DS, Addis M, Altschuler A, **Samet JH**, Labelle C, Arnsten J, Caldeiro RM, Borst DT, Stotts AL, Braciszewski JM, Szapocznik J, Bart G, Schwartz RP, McNeely J, Liebschutz JM, Tsui JI, Merrill JO, Glass JE, Lapham GT, Murphy SM, Weinstein ZM, Yarborough BJ, Bradley K. **PRimary Care Opioid Use Disorders treatment (PROUD) trial protocol: a pragmatic, cluster-randomized implementation trial in primary care for opioid use disorder treatment.** *Addict Sci Clin Pract*. 2021; 16:9.
<https://pubmed.ncbi.nlm.nih.gov/33517894/>

Coupet E Jr, D'Onofrio G, Chawarski M, Edelman EJ, O'Connor PG, Owens P, Martel S, Fiellin DA, Cowan E, Richardson L, Huntley K, Whiteside LK, Lyons MS, Rothman RE, **Pantolon M**, Hawk K. **Emergency department patients with untreated opioid use disorder: A comparison of those seeking versus not seeking referral to substance use treatment.** *Drug Alcohol Depend*. 2021 Feb 1;219:108428. doi: 10.1016/j.drugalcdep.2020.108428. Epub 2020 Nov 26.
<https://pubmed.ncbi.nlm.nih.gov/33307301/>

Cowan, E., Khan, M.R., Shastry, S., **Edelman, E. J.** **Conceptualizing the effects of the COVID-19 pandemic on people with opioid use disorder: an application of the social ecological model.** *Addict Sci Clin Pract* 16, 4 (2021).
<https://doi.org/10.1186/s13722-020-00210-w>

D'Onofrio G, Hawk KF, Herring A, Perrone J, Cowan E, McCormack R, Dziura J, Taylor A, Coupet E, **Edelman EJ**, **Pantolon MV...& Fiellin DA.** **The design and conduct of a randomized clinical trial comparing emergency department initiation of sublingual versus a 7-day extended-release injection formulation of buprenorphine for opioid use disorder: Project ED Innovation.** *Contemporary Clinical Trials*. 2021 Mar 16:106359. <https://pubmed.ncbi.nlm.nih.gov/33737199/>

Karnik NS, Campbell CI, Curtis ME, **Fiellin DA**, Ghitza U, Hefner K, Hser YI, **McHugh RK**, Murphy SM, McPherson SM, Moran L, Mooney LJ, Wu LT, Shmueli-Blumberg D, Shulman M, Schwartz RP, Stephens KA, Watkins KE, Marsden J. **Core outcomes set for research on the treatment of opioid use disorder (COS-OUD): The National Institute on Drug Abuse Clinical Trials Network protocol for an e-Delphi consensus study.** *Trials*. 2021 Jan 28;22(1):102. doi: 10.1186/s13063-021-05051-9. PMID: <https://pubmed.ncbi.nlm.nih.gov/33509278/>

Lapham G, Boudreau DM, Johnson EA, Bobb JF, Matthews AG, McCormack J, Liu D, **Samet JH**, Saxon AJ, Campbell CI, Glass JE, Rossom RC, Murphy MT, Binswanger IA, Yarborough BH, Bradley KA and PROUD Collaborative Investigators (Ahmedani B, Amoroso PJ, Arnsten JH, Bart G, Braciszewski JM, Cunningham CO, Hechter RC, Horigian VE, Liebschutz JM, Loree AM, Matson TE, McNeely J, Merrill JO, Northrup TF, Schwartz RP, Stotts AL, Szapocznik J, Thakral M, Tsui JI, Zare M). **Prevalence and treatment of opioid use disorders among primary care patients in six health systems.** *Drug Alc Depend*. *In press*.

Shulman MY, **Weiss RD**, Rotrosen J; Novo P, Costello E, Nunes EV. **Prior National Drug Abuse Treatment Clinical Trials Network (CTN) Opioid Use Disorder Trials as Background and Rationale for NIDA CTN-0100 "Optimizing Retention, Duration and Discontinuation Strategies for Opioid Use Disorder Pharmacotherapy (RDD)."** *Addict Sci Clin Pract*. 2021 Mar 6;16(1):15. doi: 10.1186/s13722-021-00223-z. <https://pubmed.ncbi.nlm.nih.gov/33676577/>

Tsui JI, Akosile MA, Lapham GT, Boudreau DM, Johnson EA, Bobb JF, Binswanger IA, Yarborough BJH, Glass JE, Rossom RC, Murphy MT, Cunningham CO, Arnsten JH, Thakral M, Saxon AJ, Merrill JO, **Samet JH**, Bart GB, Campbell CI, Loree AM, Silva A, Stotts AL, Ahmedani B, Braciszewski JM, Hechter RC, Northrup TF, Horigian VE, Bradley KA. **Prevalence and medication treatment of opioid use disorder among primary care patients with Hepatitis C and HIV.** *J Gen Intern Med*. *In press*.

Other News

Dr. Ayana Jordan (Yale University) has agreed to take on the JCOIN Equity, Diversity and Inclusion (JEDI) leadership role in collaboration with the network.