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For a full list of our past and upcoming meetings and workshops, check out this website: [OCE Meetings and Workshops.](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDIsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvYWJvdXQtZmRhL29uY29sb2d5LWNlbnRlci1leGNlbGxlbmNlL29jZS1tZWV0aW5ncy1hbmQtd29ya3Nob3BzP3V0bV9tZWRpdW09ZW1haWwmdXRtX3NvdXJjZT1nb3ZkZWxpdmVyeSIsImJ1bGxldGluX2lkIjoiMjAyMzA2MjAuNzg0ODIzODEifQ.kInMhbCKuTalg748btpCAgnVe-6TMbEfuIBWGIn5e2E/s/1256231544/br/206112872186-l) Project Socrates: Educational Opportunities  |  | | --- | | OCE has many free educational programs for hematology/oncology fellows, junior faculty, basic and translational scientists, and anyone interested in learning more about regulatory science and drug development. This includes workshops, fellowships, and webinars. Check out our [**Project Socrates**](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDMsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvYWJvdXQtZmRhL29uY29sb2d5LWNlbnRlci1leGNlbGxlbmNlL3Byb2plY3Qtc29jcmF0ZXM_dXRtX21lZGl1bT1lbWFpbCZ1dG1fc291cmNlPWdvdmRlbGl2ZXJ5IiwiYnVsbGV0aW5faWQiOiIyMDIzMDYyMC43ODQ4MjM4MSJ9.C8Ss8ZaBCEIo--qOVqnpNQuT0-kfNTsIixItblBry-8/s/1256231544/br/206112872186-l) website for more information!  [**Project Livin’ Label**](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDQsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvYWJvdXQtZmRhL29uY29sb2d5LWNlbnRlci1leGNlbGxlbmNlL3Byb2plY3QtbGl2aW4tbGFiZWw_dXRtX21lZGl1bT1lbWFpbCZ1dG1fc291cmNlPWdvdmRlbGl2ZXJ5IiwiYnVsbGV0aW5faWQiOiIyMDIzMDYyMC43ODQ4MjM4MSJ9.fn83iUuIo7R47bT-QiLHP21rXHYo4fNJ3qhgQaGFLXI/s/1256231544/br/206112872186-l) Episode 9 is now available! Listen to the “behind the scenes” discussions of the development and backstory of [**neoadjuvant nivolumab**](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDUsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmFhY3Iub3JnL3Byb2Zlc3Npb25hbHMvcG9saWN5LWFuZC1hZHZvY2FjeS9yZWd1bGF0b3J5LXNjaWVuY2UtYW5kLXBvbGljeS9yZWd1bGF0b3J5LXNjaWVuY2UtYW5kLXBvbGljeS1lZHVjYXRpb25hbC1hY3Rpdml0aWVzL3Byb2plY3QtbGl2aW4tbGFiZWwvP3V0bV9tZWRpdW09ZW1haWwmdXRtX3NvdXJjZT1nb3ZkZWxpdmVyeSIsImJ1bGxldGluX2lkIjoiMjAyMzA2MjAuNzg0ODIzODEifQ.8ppy97bO923B1s6h0--yv1iDnWf9y0r4dxMDd9GWxFg/s/1256231544/br/206112872186-l) in lung cancer. You can also find the other episodes online with free CME credit offered by AACR for each!  The [**FDA-ASCO Hematology/Oncology Fellows Workshop**](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDYsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vYXNjby5zbWFwcGx5Lm9yZy9wcm9nL09jdG9iZXJGZWxsb3dzRGF5Lz91dG1fbWVkaXVtPWVtYWlsJnV0bV9zb3VyY2U9Z292ZGVsaXZlcnkiLCJidWxsZXRpbl9pZCI6IjIwMjMwNjIwLjc4NDgyMzgxIn0.uNsfcA4jyJdlpSYCcrkXG-8JUjBG5mg0lDoOEGXNP7Y/s/1256231544/br/206112872186-l) continues in its 9th year.  This day-long hybrid workshop will discuss clinical trial design, endpoints, eligibility criteria, expedited pathways, expanded access, and much more! **Applications will be accepted  July 5 – July 26, 2023**.  The[**FDA-AACR Oncology Educational Fellowship**](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDcsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmFhY3Iub3JnL3Byb2Zlc3Npb25hbHMvcG9saWN5LWFuZC1hZHZvY2FjeS9yZWd1bGF0b3J5LXNjaWVuY2UtYW5kLXBvbGljeS9mZGEtYWFjci1vbmNvbG9neS1lZHVjYXRpb25hbC1mZWxsb3dzaGlwLz91dG1fbWVkaXVtPWVtYWlsJnV0bV9zb3VyY2U9Z292ZGVsaXZlcnkiLCJidWxsZXRpbl9pZCI6IjIwMjMwNjIwLjc4NDgyMzgxIn0.SlASYBjQnr1PZVEQLSC60w-FVvaKJ7cN37lx_3xAXqM/s/1256231544/br/206112872186-l) is a year-long fellowship held once a month, primarily over Zoom, consisting of a mix of didactics and case-based small group discussions. The fellowship ends with a mock ODAC held at FDA White Oak. **Applications will be accepted June 1 – August 14, 2023**.  Oncology fellowship program directors: if you are interested in having FDA Oncology speak to your fellows, reach out to us at [projectsocrates@fda.hhs.gov](mailto:projectsocrates@fda.hhs.gov)**!** Recent FDA Oncology Approvals We recently approved these oncology products – take a look at the product labeling to learn about indications, dosage and administration, adverse reactions, trial design, efficacy results, and much more!  **June 15, 2023:** [**Columvi (glofitamab-gxbm)**](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDgsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvZHJ1Z3MvZHJ1Zy1hcHByb3ZhbHMtYW5kLWRhdGFiYXNlcy9mZGEtZ3JhbnRzLWFjY2VsZXJhdGVkLWFwcHJvdmFsLWdsb2ZpdGFtYWItZ3hibS1zZWxlY3RlZC1yZWxhcHNlZC1vci1yZWZyYWN0b3J5LWxhcmdlLWItY2VsbD91dG1fbWVkaXVtPWVtYWlsJnV0bV9zb3VyY2U9Z292ZGVsaXZlcnkiLCJidWxsZXRpbl9pZCI6IjIwMjMwNjIwLjc4NDgyMzgxIn0.0skTV0upqCsmGh0EdN94F5OBBYdsYGQGChJT_bJ5kQI/s/1256231544/br/206112872186-l) for relapsed or refractory diffuse large B-cell lymphoma, not otherwise specificized or large B-cell lymphoma arising from follicular lymphoma – accelerated approval.  **May 31, 2023:** [**Olaparib with abiraterone and prednisone (or prednisolone)**](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDksInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvZHJ1Z3MvZHJ1Zy1hcHByb3ZhbHMtYW5kLWRhdGFiYXNlcy9mZGEtYXBwcm92ZXMtb2xhcGFyaWItYWJpcmF0ZXJvbmUtYW5kLXByZWRuaXNvbmUtb3ItcHJlZG5pc29sb25lLWJyY2EtbXV0YXRlZC1tZXRhc3RhdGljLWNhc3RyYXRpb24_dXRtX21lZGl1bT1lbWFpbCZ1dG1fc291cmNlPWdvdmRlbGl2ZXJ5IiwiYnVsbGV0aW5faWQiOiIyMDIzMDYyMC43ODQ4MjM4MSJ9.bcISA49iRQq7TeK4_csxZpQRZHYmu198cehWTayt2_8/s/1256231544/br/206112872186-l) for BRCA-mutated metastatic castration-resistant prostate cancer – regular approval.  **May 18, 2023:** [**Epcoritamab-bysp**](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMTAsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvZHJ1Z3MvZHJ1Zy1hcHByb3ZhbHMtYW5kLWRhdGFiYXNlcy9mZGEtZ3JhbnRzLWFjY2VsZXJhdGVkLWFwcHJvdmFsLWVwY29yaXRhbWFiLWJ5c3AtcmVsYXBzZWQtb3ItcmVmcmFjdG9yeS1kaWZmdXNlLWxhcmdlLWItY2VsbD91dG1fbWVkaXVtPWVtYWlsJnV0bV9zb3VyY2U9Z292ZGVsaXZlcnkiLCJidWxsZXRpbl9pZCI6IjIwMjMwNjIwLjc4NDgyMzgxIn0.lhVhFenjOhEfMcdxhzNZWBuZ-ezK3fwMzk8wvML_SKw/s/1256231544/br/206112872186-l) for relapsed or refractory diffuse large B-cell lymphoma and high-grade B-cell lymphoma – accelerated approval.  **April 19, 2023:** [**Polatuzumab vedotin-piqq**](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMTEsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvZHJ1Z3MvcmVzb3VyY2VzLWluZm9ybWF0aW9uLWFwcHJvdmVkLWRydWdzL2ZkYS1hcHByb3Zlcy1wb2xhdHV6dW1hYi12ZWRvdGluLXBpaXEtcHJldmlvdXNseS11bnRyZWF0ZWQtZGlmZnVzZS1sYXJnZS1iLWNlbGwtbHltcGhvbWEtbm90P3V0bV9tZWRpdW09ZW1haWwmdXRtX3NvdXJjZT1nb3ZkZWxpdmVyeSIsImJ1bGxldGluX2lkIjoiMjAyMzA2MjAuNzg0ODIzODEifQ.TrzFiZ9BJe1iYyQwMb-qbNoguazAo9N3HZ35rh-T90Y/s/1256231544/br/206112872186-l) for previously untreated diffuse large B-cell lymphoma, not otherwise specified, and high-grade B-cell lymphoma – regular approval.  **Interested in learning more?**Tune into our FDA Oncology Podcast. You can also take a  look at this website [**How to Use Product Labeling**](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMTIsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvYWJvdXQtZmRhL29uY29sb2d5LWNlbnRlci1leGNlbGxlbmNlL2hvdy1kby1pLXVzZS1wcmVzY3JpcHRpb24tZHJ1Zy1sYWJlbGluZz91dG1fbWVkaXVtPWVtYWlsJnV0bV9zb3VyY2U9Z292ZGVsaXZlcnkiLCJidWxsZXRpbl9pZCI6IjIwMjMwNjIwLjc4NDgyMzgxIn0.QZj_S2DcQeb3eFlpi6-qJ8VTOUwwTcx97b4oiTNHvwU/s/1256231544/br/206112872186-l) and find a full list of [**FDA oncology approvals**](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMTMsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvZHJ1Z3MvcmVzb3VyY2VzLWluZm9ybWF0aW9uLWFwcHJvdmVkLWRydWdzL29uY29sb2d5LWNhbmNlci1oZW1hdG9sb2dpYy1tYWxpZ25hbmNpZXMtYXBwcm92YWwtbm90aWZpY2F0aW9ucz91dG1fbWVkaXVtPWVtYWlsJnV0bV9zb3VyY2U9Z292ZGVsaXZlcnkiLCJidWxsZXRpbl9pZCI6IjIwMjMwNjIwLjc4NDgyMzgxIn0.AXSOiH1OqkL9vfe5fMoiBvwzUHiPFz4n_uYWAcpDJ4g/s/1256231544/br/206112872186-l) online! OCE Spotlight – Get to Know Us! |  |  |  |  | | --- | --- | --- | | Kim |  | **Nina Kim** is a medical oncologist and a clinical reviewer on the acute leukemia, MDS, and CML team. She has a research interest in clinical trial endpoints and drug development for MDS. In her spare time, she enjoys spending time with her husband and 5-month-old son, exploring DC, and watching Formula 1. |  |  | | --- | |  |  |  |  |  | | --- | --- | --- | | **Brian Heiss** is a medical oncologist, GU oncology clinical reviewer, and member of FDA’s dosage optimization initiative, Project Optimus. He has research interests in post marketing dosage optimization and prostate cancer intermediate endpoints. In his spare time, he gardens, bikes the trails in and around DC, and supports the Washington Capitals and Nationals. |  | Brian | | | | |

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