

### CPTR: Revitalizing the Pipeline:

1. Talwar, Amish, et al. "Tuberculosis—United States, 2018." *Morbidity and Mortality Weekly Report* 68.11 (2019): 257.
2. "Trends in Tuberculosis, 2019." *Center for Disease Control and Prevention*. Accessed 16 December 2020. <https://www.cdc.gov/tb/publications/factsheets/statistics/tbtrends.htm>
3. Annabel, B., D. Anna, and M. Hannah. "Global tuberculosis report 2019." Geneva: World Health Organization (2019).
4. Robinson, Sally, and Robert Giffin, eds. *Addressing the threat of drug-resistant tuberculosis: a realistic assessment of the challenge: workshop summary*. National Academies Press, 2010. pp. 82-85.
5. Zumla, Alimuddin I., et al. "New antituberculosis drugs, regimens, and adjunct therapies: needs, advances, and future prospects." *The Lancet infectious diseases* 14.4 (2014): 327-340.
6. "Tuberculosis Therapeutic Area User Guide v2.0." *CDISC*. Accessed 16 December 2020. <https://www.cdisc.org/standards/therapeutic-areas/tuberculosis>
7. European Medicines Agency. *qualification-opinion-vitro-hollow-fibre-system-model-tuberculosis-hfs-tb\_en.pdf*. Published Rev 2015. Accessed 16 December 2020. [https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/qualification-opinion-vitro-hollow-fibre-system-model-tuberculosis-hfs-tb\\_en.pdf](https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/qualification-opinion-vitro-hollow-fibre-system-model-tuberculosis-hfs-tb_en.pdf)
8. Critical Path Institute. "TB ReFLECT – Meta-analysis of Phase III Quinolone Data." *Critical Path Institute*. Accessed 16 December 2020. <https://c-path.org/programs/cptr/cptr-tools/modeling-simulation-tools/tb-reflect-meta-analysis-of-phase-iii-quinolone-data/>
9. Gardner, Iain, and Oliver Hatley. "New Tools Support Developing Better TB Drugs." *Best of the Blog* 2017: 39.
10. Talwar, Amish, et al. "Tuberculosis—United States, 2018." *Morbidity and Mortality Weekly Report* 68.11 (2019): 257.
11. U.S Food and Drug Administration. *204384s000lbl.pdf*. Published Rev 2012. Accessed 16 December 2020. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2020/202811s016lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/202811s016lbl.pdf)
12. TB Alliance. *Pretomanid\_Full-Prescribing-Information.pdf*. Published Rev 2019. Accessed 16 December 2020. [https://www.tballiance.org/sites/default/files/assets/Pretomanid\\_Full-Prescribing-Information.pdf](https://www.tballiance.org/sites/default/files/assets/Pretomanid_Full-Prescribing-Information.pdf)

### PRO Consortium: Integrating Voices of Patients, Enabling Future Therapies:

1. NIDDK. Irritable Bowel Syndrome (IBS) | NIDDK. *National Institute of Diabetes and Digestive and Kidney Diseases*. Accessed 4 December 2020. <https://www.niddk.nih.gov/health-information/digestive-diseases/irritable-bowel-syndrome>
2. Canavan, Caroline, Joe West, and Timothy Card. "The epidemiology of irritable bowel syndrome." *Clinical epidemiology* 6 (2014): 71.
3. Camilleri, Michael, et al. "Reviews in Basic and Clinical Gastroenterology and Hepatology." *Gastroenterology* 135.6: 1877-1891.
4. M Ervin, Claire, and Allen W Mangel. "Clinical trials in irritable bowel syndrome: a review." *Reviews on recent clinical trials* 8.1 (2013): 9-22.
5. Fehnel, Sheri E., et al. "Development of the diary for irritable bowel syndrome symptoms to assess treatment benefit in clinical trials: Foundational Qualitative Research." *Value in Health* 20.4 (2017): 618-626.
6. *202811s016lbl.pdf*. Published Rev 2020. Accessed December 4, 2020. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2020/202811s016lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/202811s016lbl.pdf)

### Polycystic Kidney Disease Outcomes Consortium: Impact on Industry and Patients:

1. Wouters, O. J., M. McKee, and J. Luyten. "Estimated research and development investment needed to bring a new medicine to market, 2009-2018 [published March 3, 2020]." *JAMA*.
2. Harris, Peter C., and Vicente E. Torres. "Polycystic kidney disease." *Annual review of medicine* 60 (2009): 321-337.
3. PKD Foundation. "What is ADPKD?" *PKD Foundation*. Accessed 18 December 2020. <https://pkdcure.org/what-is-adpkd/>