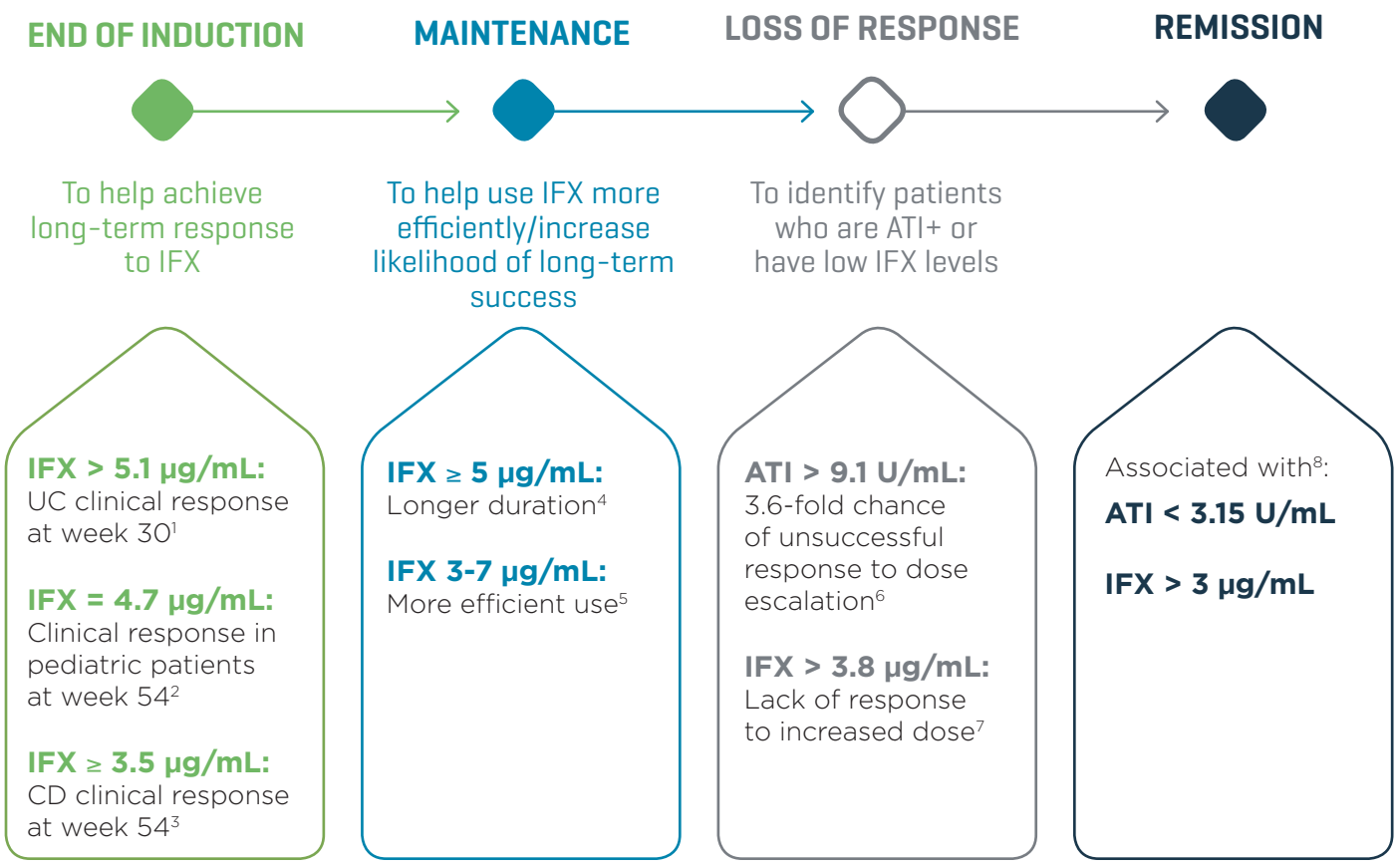
Monitor & Optimize

PROMETHEUS® Anser® IFX

Monitor with PROMETHEUS® Anser® IFX to help optimize infliximab (IFX) therapy during induction, maintenance, and loss of response

Clinical Associations Between Serum IFX and Antibodies to IFX (ATI) Levels in IBD[1-8]



Know their IFX levels. Build your plan.

PROMETHEUS®
Anser® IFX

LEVELS	Multiple Studies Associated Serum IFX and/or ATI Levels with Outcomes[1-8]
Induction	
IFX > 5.1 µg/mL	**ACT-1 and ACT-2 post hoc analysis of UC patients:** IFX > 5.1 µg/mL associated with clinical response in UC patients at week 30[1,a]
IFX = 4.7 µg/mL	**Prospective observational study of 46 pediatric IBD patients:** IFX = 4.7 µg/mL (median level) predictive of persistent remission (PR) in pediatric IBD patients at week 54 vs 2.6 µg/mL for patients not in PR (P = 0.03)[2,b]
IFX ≥ 3.5 µg/mL	**ACCENT-1 post hoc analysis of CD patients (n = 71 in 5 mg/kg group):** IFX ≥ 3.5 µg/mL associated with CD clinical response at week 54 without dose escalation[3,a,c]
Maintenance	
IFX ≥ 5 µg/mL	**Retrospective, dose-adjustment study of 126 IBD patients:** IFX ≥ 5 µg/mL at trough associated with longer duration of IFX therapy without flares (P < 0.0001)[4,b]
IFX 3-7 µg/mL	**TAXIT randomized, controlled dose-escalation trial of 43 CD and 26 UC patients in stable clinical response:** IFX 3-7 µg/mL at trough associated with higher proportion of CD patients in remission (P = 0.02) and more efficient use of IFX (P < 0.001)[5,a,d]
Loss of response (LOR)	
IFX > 3.8 µg/mL	**Retrospective study of 247 IBD patients with 188 IFX LOR events:** IFX > 3.8 µg/mL associated with lack of response to IFX dose increase[7,e]
ATI > 9.1 U/mL	**Retrospective study where 1,232 serum samples drawn just prior to IFX infusion from 64 CD and 26 UC patients were analyzed:** ATI > 9.1 U/mL associated with 3.6-fold likelihood of unsuccessful intervention (P = 0.003)[6,f]
Remission	
IFX > 3 µg/mL	**Four prospective, randomized clinical trials where 1,487 serum samples from 483 CD patients on maintenance IFX were analyzed:** IFX > 3 µg/mL associated with remission (area under the curve [AUC] = 0.681; 95% CI 0.632-0.731)[8,g]
ATI < 3.15 U/mL	**Four prospective, randomized clinical trials where 1,487 serum samples from 483 CD patients on maintenance IFX were analyzed:** ATI < 3.15 U/mL associated with remission (AUC = 0.632; 95% CI 0.589-0.676)[8,f]

[a]Serum IFX levels were reported based off enzyme linked immunoassay (ELISA).
[b]Serum IFX levels were reported based off PROMETHEUS® Anser® IFX and ELISA.
[c]Patients with and without durable sustained response at week 54 had median 4 and 1.9 µg/mL IFX levels, respectively (P = 0.033).
[d]Proportion of CD patients in remission after optimization was 88% vs 65% before dose escalation.
[e]Serum IFX and ATI levels were reported based on ELISA.
[f]Serum ATI levels were reported based off PROMETHEUS Anser IFX.
[g]Serum IFX levels were reported based off PROMETHEUS Anser IFX.

References: 1. Adedokun OJ, Sandborn WJ, Feagan BG, et al. Association between serum concentration of infliximab and efficacy in adult patients with ulcerative colitis. *Gastroenterology.* 2014;147(6):1296-1307. **2.** Singh N, Rosenthal CJ, Melmed GY, et al. Early infliximab trough levels are associated with persistent remission in pediatric patients with inflammatory bowel disease. *Inflamm Bowel Dis.* 2014;20(10):1708-1713. **3.** Cornillie F, Hanauer SB, Diamond RH, et al. Postinduction serum infliximab trough level and decrease of C-reactive protein level are associated with durable sustained response to infliximab: a retrospective analysis of the ACCENT I trial. *Gut.* 2014;63(11):1721-1727. **4.** Vaughn BP, Martinez-Vazquez M, Patwardhan VR, Moss AC, Sandborn WJ, Cheifetz AS. Proactive therapeutic concentration monitoring of infliximab may improve outcomes for patients with inflammatory bowel disease: results from a pilot observational study. *Inflamm Bowel Dis.* 2014;20(11):1996-2003. **5.** Vande Casteele N, Ferrante M, Van Assche G, et al. Trough concentrations of infliximab guide dosing for patients with inflammatory bowel disease. *Gastroenterology.* 2015;148(7):1320-1329. **6.** Vande Casteele N, Gils A, Singh S, et al. Antibody response to infliximab and its impact on pharmacokinetics can be transient. *Am J Gastroenterol.* 2013;108(6):962-971. **7.** Yanai H, Lichtenstein L, Assa A, et al. Levels of drug and antidrug antibodies are associated with outcome of interventions after loss of response to infliximab or adalimumab. *Clin Gastroenterol Hepatol.* 2015;13(3):522-530. **8.** Vande Casteele N, Khanna R, Levesque BG, et al. The relationship between infliximab concentrations, antibodies to infliximab and disease activity in Crohn's disease. *Gut.* 2015;64(10):1539-1545.

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