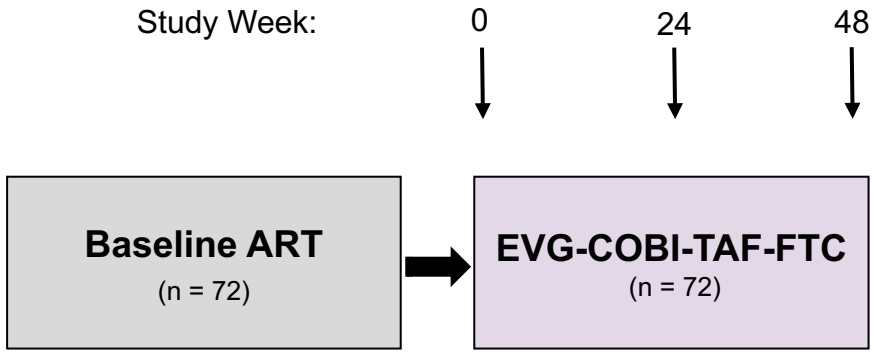
Elvitegravir-Cobicistat-TAF-FTC in Hepatitis B Coinfection

Study 1249

National HIV Curriculum

Elvitegravir-Cobicistat-TAF-FTC in HIV/HBV Coinfection Study 1249: Design

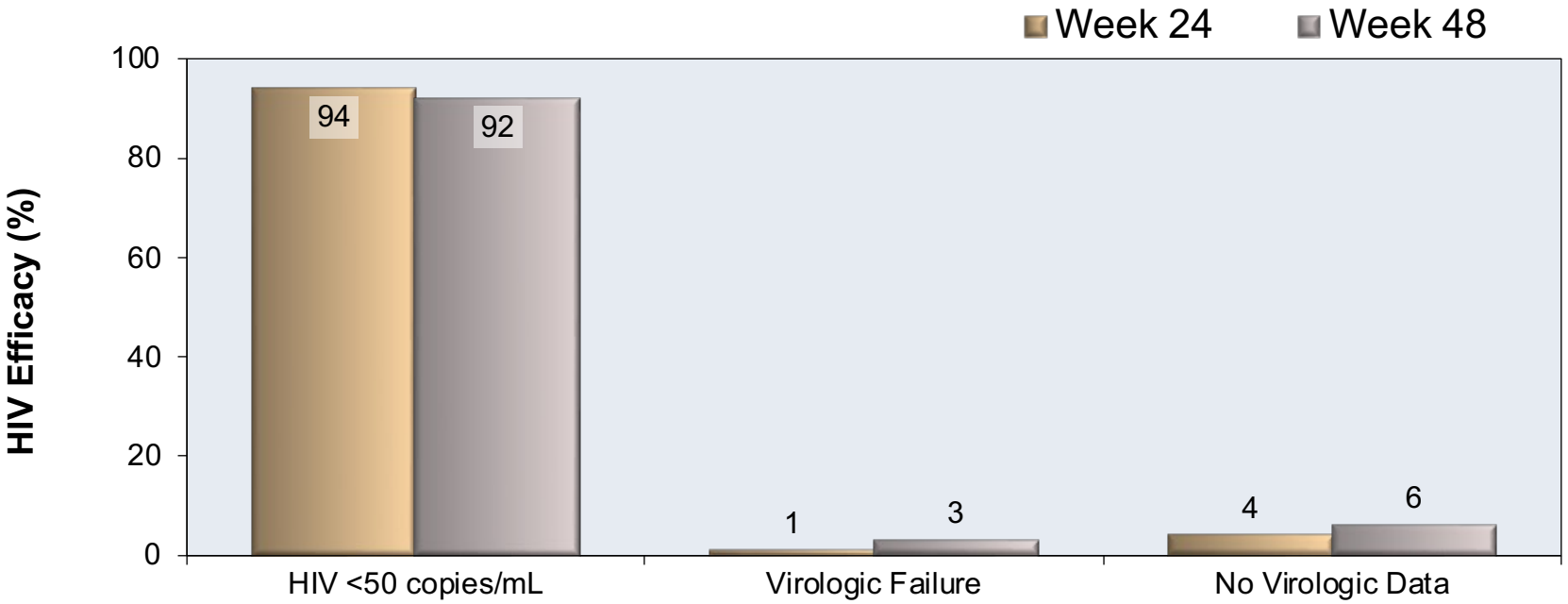
- **Background**: Open-label, single-arm, phase 3b trial evaluating switching to once-daily elvitegravir-cobicistat-tenofovir alafenamide-emtricitabine in adults with HIV and HBV
- **Inclusion Criteria** (n = 72)
  - Adults with HIV and chronic HBV
  - HIV RNA <50 copies/mL for ≥6 months
  - Stable ART regimen for ≥4 months
  - CD4 ≥200 cells/mm^3
  - CrCl ≥50 mL/min, ALT ≤10x ULN
  - No cirrhosis, HCC, HCV, hepatitis D
- **Treatment Arms**
  - Switch to EVG-COBI-TAF-FTC



Source: Gallant J, et al. J Acquir Immune Defic Syndr. 2016;73:294-8.

Elvitegravir-Cobicistat-TAF-FTC in HIV/HBV Coinfection Study 1249: Result

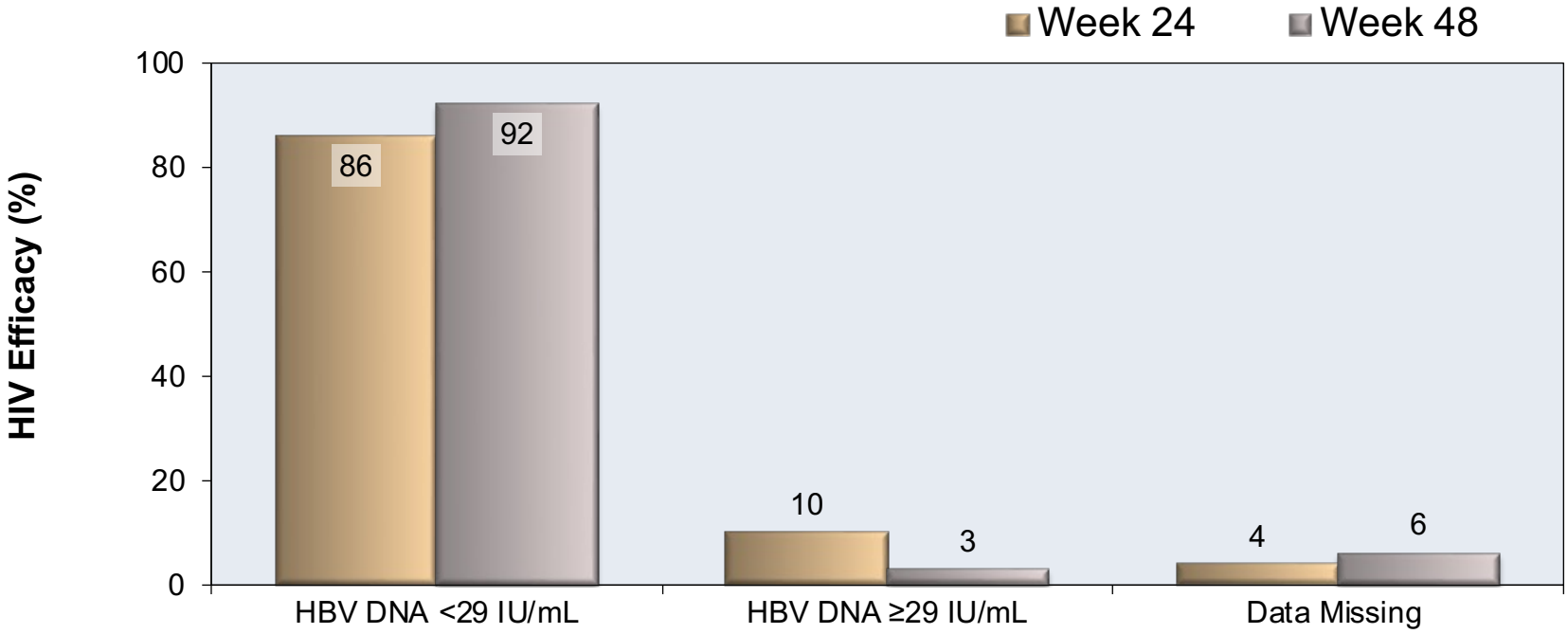
HIV Efficacy at Weeks 24 and 48



Source: Gallant J, et al. J Acquir Immune Defic Syndr. 2016;73:294-8.

Elvitegravir-Cobicistat-TAF-FTC in HIV/HBV Coinfection Study 1249: Result

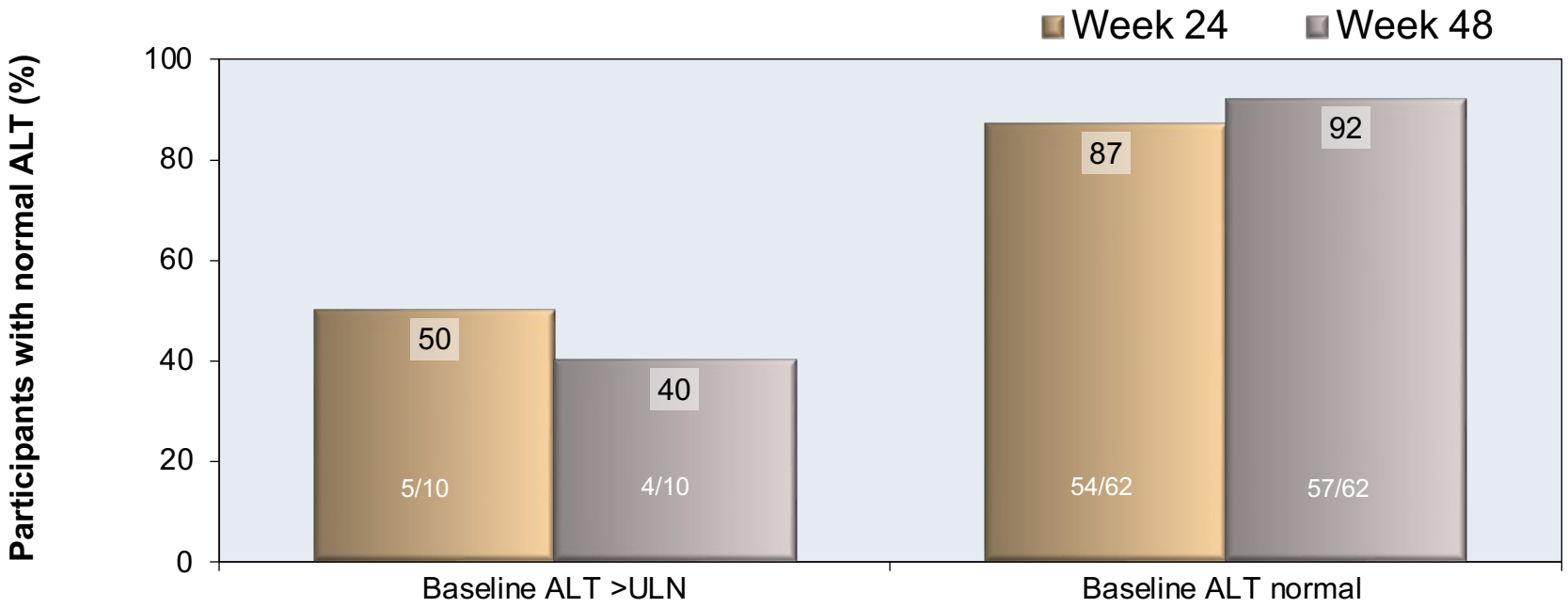
HBV Efficacy at Weeks 24 and 48, Missing = Failure



Source: Gallant J, et al. J Acquir Immune Defic Syndr. 2016;73:294-8.

Elvitegravir-Cobicistat-TAF-FTC in HIV/HBV Coinfection Study 1249: Subgroup Analysis Result

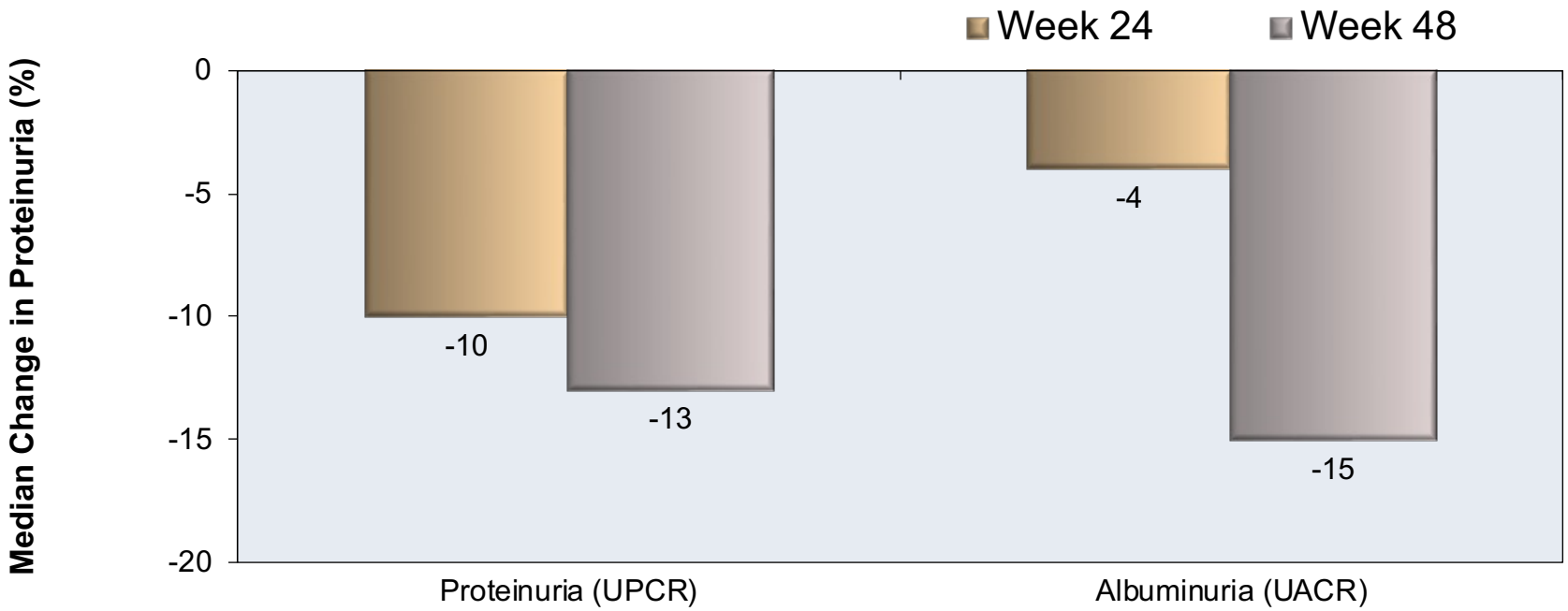
ALT Measurement at Weeks 24 and 48



Source: Gallant J, et al. J Acquir Immune Defic Syndr. 2016;73:294-8.

Elvitegravir-Cobicistat-TAF-FTC in HIV/HBV Coinfection Study 1249: Result

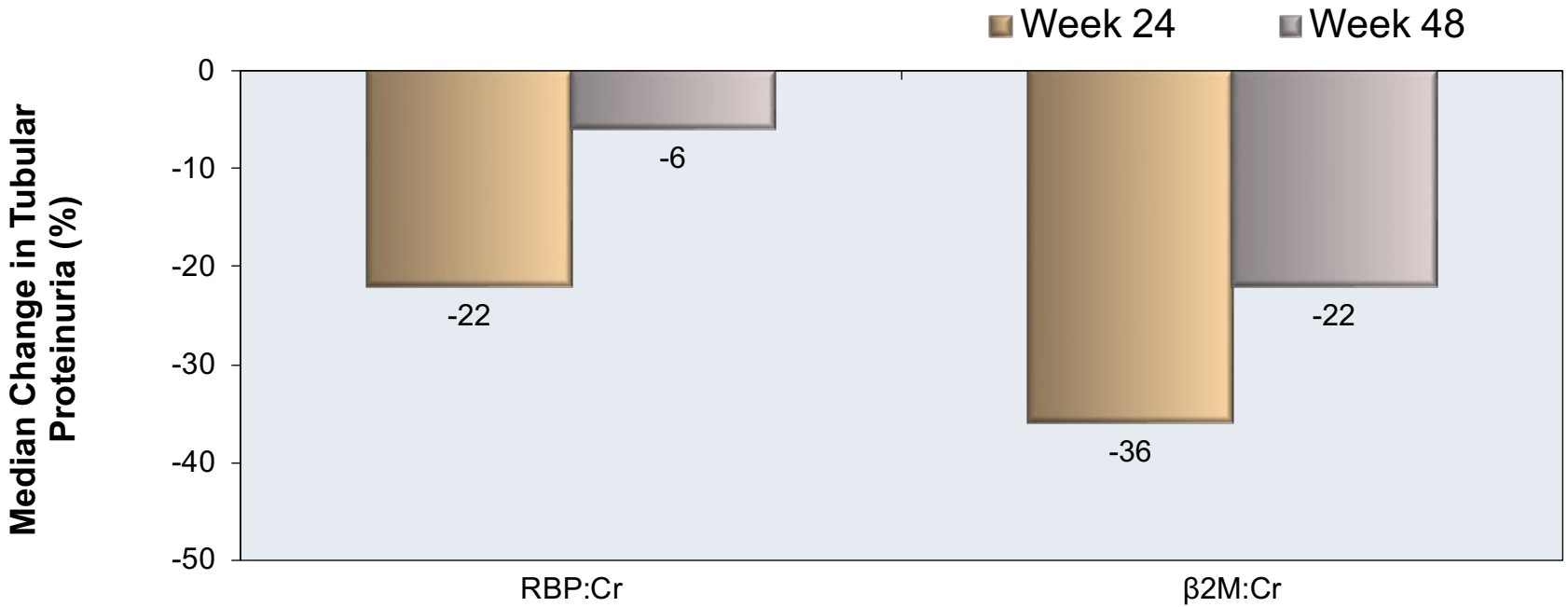
Changes in General Proteinuria at Weeks 24 and 48 from Baseline



Source: Gallant J, et al. J Acquir Immune Defic Syndr. 2016;73:294-8.

Elvitegravir-Cobicistat-TAF-FTC in HIV/HBV Coinfection Study 1249: Result

Changes in Tubular Proteinuria at Weeks 24 and 48 from Baseline



RBP:Cr = retinol binding protein:creatinine ratio; β2M:Cr = beta-2 microalbumin:creatinine ratio

Source: Gallant J, et al. J Acquir Immune Defic Syndr. 2016;73:294-8.

Elvitegravir-Cobicistat-TAF-FTC in HIV/HBV Coinfection Study 1249: Conclusions

Interpretation: “In this first study in HIV/HBV-coinfected participants with suppressed HIV infection, E/C/F/TAF was effective against HIV and HBV, well tolerated, and demonstrated improvements in renal and bone safety consistent with the clinical profile of TAF. These data support the use of E/C/F/TAF in treating HIV/HBV coinfections.”

Source: Gallant J, et al. J Acquir Immune Defic Syndr. 2016;73:294-8.

Acknowledgments

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