

Oncore Financials and High Per Patient Revenue Clinical Trials – Impact of Discharged Not Final Billed

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1. Background

Institutions supporting the conduct of clinical trials face financial risk when holding billing of both pharmaceutical sponsors and insurance payors for long periods of time leading to high discharged not final billed (DNFB) amounts. DNFB is part of Clinical Research Revenue Cycle standard process for billing at our institution. However, due to steps in the process associated with Oncore Financials, large DNFB holds have become common. These holds are primarily due to frequent protocol amendments that have financial impact, updates to the Oncore calendar for visit certification, and additional internal process validation. The institution is at risk of failing to meet timely billing when steps within Oncore Financials are not completed for each patient visit within the timeframe allowed. Being in DNFB delays reimbursements from payors and based on the insurer's timeline for timely filing, billing segregation and final billing could take place after these windows close, and institutions are forced to absorb these costs. Additionally, DNFB poses a challenge for tracking the financial health of a program, fully understanding a clinical trial's revenue vs cost, and accurate financial planning.

2. Goals

Expand our knowledge of the Clinical Trials Office's (CTO) impact on DNFB and revenue write-offs for high per patient budget trials. Further our understanding of expected recognized revenue from DNFB for financial planning. Recognized revenue is based on clinical research coordinators/nurses completing visit certifications on a budgeted Oncore calendar with revenue associated.

3. Solutions and Methods

We created a Power BI DNFB tracking tool to summarize current and historical DNFB that can be assessed for the CTO.

We performed a retrospective analysis to evaluate revenue write offs due to untimely filing within the CTO and calculated the average number of days DNFB was held during 2024. We also investigated the average percent of DNFB that is converted to recognized revenue stratified by investigator-initiated trials (IITs) and pharmaceutical sponsored trials.

4. Outcomes

Utilizing the Power BI DNFB tracking tool, we can now evaluate the historical amount of DNFB per management group per month and further stratified per individual clinical trials. This is graphed to compare total balance amount, sponsor billed, and untimely filing over the last calendar year. Historical DNFB is also categorized by Amendment Review, Calendar Maintenance, Certification Review, Compliance, and Research Validation in alignment with Moffitt's Billing Exception Worklist (BEW). With the use of this data, total DNFB has moved from \$100 million (at January 2024 month end) to \$23 million (at January 2025 month end).

By identifying an average percent of DNFB that is expected recognized revenue, CTO leaders have a better understanding of their individual program's financial health. This anticipated revenue can be utilized to more accurately plan fiscal goals and for growth.'

5. Learned and Future Directions

The Power BI DNFB tracking tool provides current DNFB insights and month-end analyses define billing segregation (insurance vs. sponsor). Future directions include evaluating opportunities within Oncore Financials and institutionally to speed up DNFB bill hold release. Opportunities include, but are not limited to, evaluating service level agreements (SLAs) for amendment processing and accelerating budget/contract negotiations.