

EFS Budgeting Best Practices

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Edwards

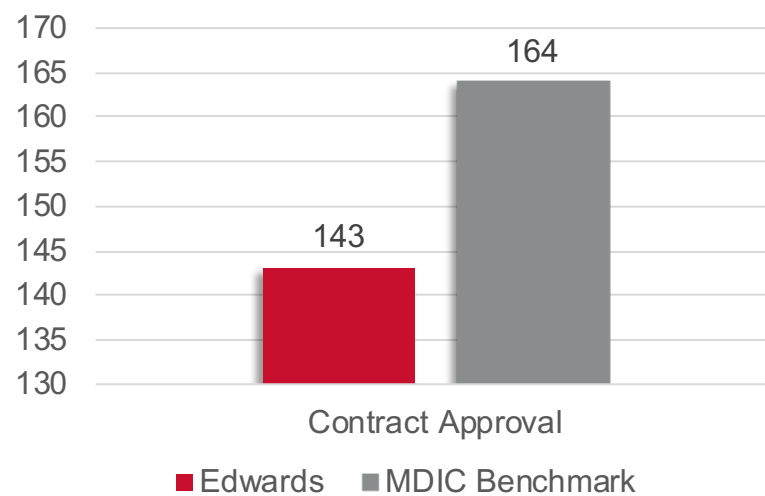
Professional Background

- Sr. Manager, Clinical Operations at Edwards Lifesciences
 - Contracts, budgets, payments, system optimization
- Manager, Regulatory & Contracts Manager at Edwards Lifesciences
- Sr. Legal Analyst, Bausch & Lomb
- Paralegal, ISTA Pharmaceuticals
- Paralegal, Davita Healthcare

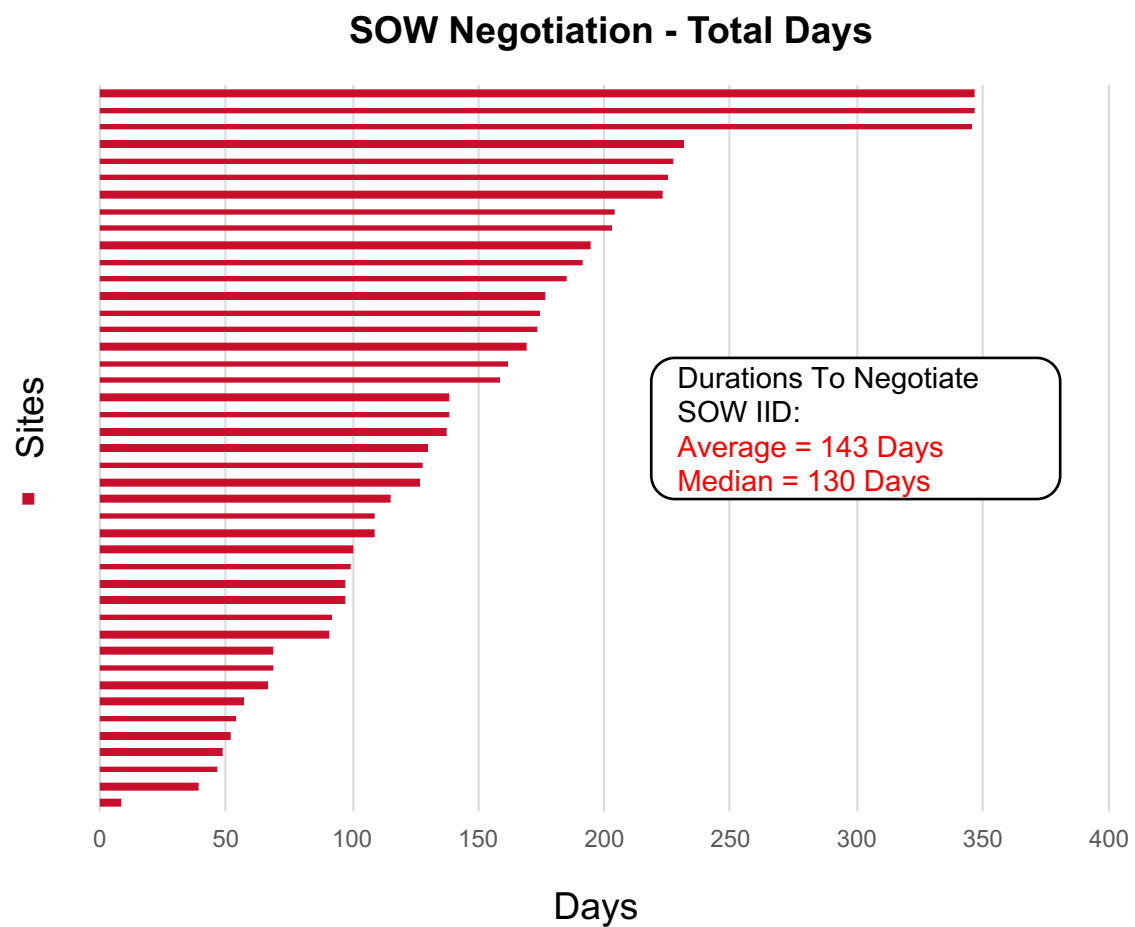
EFS Experience at Edwards

- Clinical trial group running 6 EFS in US in less than 3 years, plus pivotal trials
- Contracts & budgets can make the difference at start-up
- Budget review can be tedious and time consuming

Edwards Contract Approval Timelines in Days (Average)



SOW Negotiation Timelines



Very large variance – but overall still faster than signing one-time agreements

Results Achieved for Budget Negotiations

- Sped up budget approval process & contract execution timelines
- Creation of budget negotiation guidelines for Clinical Contracts team = consistency
- All budgets within fair market value (FMV)

Examples of Best and Worst Performance

SOW Negotiation	
Sites	Total Days
Site A	9
Site B	39
Site C	47
Site D	49
Site E	52
Site F ((MCTA in place)	227
Site G (No MCTA)	232
Site H (No MCTA)	346
Site I (No MCTA)	347
Site J (No MCTA)	347



Fastest sites have MCTAs & are quick to respond on budgets & SOW



Slowest sites don't have MCTAs & have very slow budget response times

Tips & Tricks for Timely Budget Negotiations

- Staff appropriately & train, train, train!
- Preparation of SOWs & budget once the trial has a draft protocol
 - Send out SOWs & Budgets within 48 hours of regulatory package sent to sites
- Establish clear budget approval guidelines
- From the budget templates, each site budget is customized based on previously negotiated rates
- Creation of budget comparison table showing rates with sites across all Edwards' trials
- Established internal review & follow-up timelines
 - Contracts analyst has 24-48 hrs to review site feedback or seek manager help
 - Requirement to follow-up with Sites every 3-5 days if a budget is with Site
 - Escalate to trial management if site is not responsive

Recommendations for General Improvement

- Staff appropriately
- Leverage prior rates
- Collaborate with the other side – this is not a battle!
- Look at overall budget – not just one line item



Questions

