**Data after 2010 promotion to a Group Head:**

**Data related to people and teams’ management**

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| --- | --- | --- | --- | --- |
| Year | Teams | Number of people | Number of people promoted | Different meeting preparation and highlights |
| 2010 | CP, OTM, OBBI | 9 | 3 | 1. F2F meeting preparation for - CP, OTM BDM and CDRR. 2. HYD business road map meetings |
| 2011 | CP, OTM, OBBI, DRP, TKI | 25 | 5 | 1. OTM F2F meeting preparation, 2. DRP F2F meeting in the US 3. David Epstein meeting 4. Joe Jimenez meeting |
| 2012 | CP, OTM, DRP, TKI, LSH | 24 | 4 | 1. CP Basel India BDM meetings co-chair 2. Initiated DRP forum |
| 2013 | DRP, LSH, LDE | 22 = 10 + 12 FSPs | 3 + 3 LSA managers | 1. LSH team set-up and training of 10 LSPs 2. Informal support on the TKI submission 3. Informal support on the LDK submission on many efficacy outputs, graphs, etc. 4. DRP initiative reports ~30 reports programmed which are currently used in RADAR 5. Alessandro Riva meeting |
| 2014 | DRP, LSH, LDE, BKM, Standards team | ~25 | 4, 2 promotions were for the LSPs who were not promoted at all. | 1. Almost 35 odd different Interim analysis, DMCs, Full Locks, etc. supported by the LSH team. 2. LDE submission support, Inclusion in the Standards team, responsibility of 8 different activities within standards (OSO, TFL, RECIST, Data transparency, eCRS, CTC, ANP) |
| 2015 | LDE, BKM, Standards team | 10 |  |  |

**People related: strategic contribution or strategy initiation/conception and other non-clinical activities**

1. Contributions to the Roadmap 2015 and other parts of the overall strategy to grow the group in India (2011 – 2013).
2. Contributed in setting up the CDRR OTM meeting here in Hyderabad, working on logistics + the agenda items for the 2 and ½ days of meeting (2013).
3. Defining the job descriptions for LSH, DRP manager and LSPs.
4. “LSH analyst role” – which remained a concept only
5. Creation of DRP Programmer Profile role along with Anne and Eric. (2011).
6. Initiated the Global Oncology LSP forum which runs even today.
7. Contribution to RACI chart for BDM
8. Retained Eric even after his resignation
9. GEP (Sudarshan, Prabhakar) and DCP (Chandu, Surender) candidates identified from TCO
10. Present SR functional training for programmers.
11. Mentoring the Biostatistician Rupam to help understand clinical trials and clinical domain
12. Various slides for Lira and other LT meetings on people, maturity in role, footprint, and butterfly plots, etc.
13. Interview of almost each and every candidate (ongoing)
14. Knowledge sharing sessions for new programmers to teach them
    1. how to link Protocol, CRF, RAPs and the TFLs to each other, how to cross check the outputs, FDA label cross comparison
    2. Presented a paper on PFS in RECIST
    3. 44% outlier data,
    4. How to name drugs,
    5. Anscombe’s quartet,
    6. PK QT analysis for BEZ
15. Inspired Chandu to join PhD course (2014).
16. Transitioned Susmita Sanyal, Suresh Chenji, Prasanna N from programming teams to the biostatistics team (2010 – 2012).
17. Coordinating the Business Review Meeting slide updates for the Oncology group in India to the site leadership team (2010-2011).
18. Transition Naveen and Raj in SR from SPS.
19. Identification of the FSP teams and audit them (Sristek, Cognizant, TCS -2010, 2011).
20. Taught in Pharmacy colleges, alternative medicine collages (ongoing)
21. Func.E (Functional excellence) initiative.

**CDRR Communication initiative (2011):**

1. Development of CDRR SharePoint site as a part of Communication initiative.
2. Transfer of training material from various Lotus Notes databases to SharePoint area.

**Function related initiatives:**

1. BIMO initiative
2. First time right initiative
3. PSP22 review
4. CFAST breast cancer document review
5. Contributions to various CP and OTM initiatives for standardizing RAPs, programs.
6. Contributions to the CP PK macros and testing.
7. Effective use of new PK macros to reduce the amount of time needed for PK programming.
8. M8 standardization, STL usage for CP studies, Working with CRO.
9. OBBI tool box with programs written in R and SAS.
10. Support Metrics reports for Jreview (2011).
11. Participation in User testing for CT4 to Jreview migration (2011).
12. A workshop on DR processes to streamline the whole process from it being driven as “IT ticket” system to replicating how SR function works (2011)
13. Drug Drug Interaction dataset for easy identification of treatment types
14. SAE macro for reconciliation.
15. Created SR algorithm matrix along with Jia (2010).

**Hyderabad Site level initiatives:**

1. Series of presentations to the ONC DM team from SR
2. Local Exchange initiative talk on Ayurveda (Indian alternative medicine) and explaining my work till date
3. Support an external doctor in Ayurvedic medicine to find a career with Novartis.
4. Collaboration with the GENMEDs for SAS day events, speaker in the forums
5. Support the training for PVDM team on SAS

**Data related to the submissions**

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| --- | --- | --- |
| Year | Teams | Submission |
| 2010 | CP, OTM, OBBI | 1. SOM230 – Cushing’s disease (sc) [Q2, 2010 EMEA] and [Q4, 2010 FDA]. 2. LBH589 – Hodgkin’s CSPD preparation pooling of 14 studies as well as study level activities. 3. Close out of SOM230B/C legacy studies – 10. 4. ICL670A CP old formulation 5. AMN107C 4 studies 6. RAD001X CP 2 Chinese submission studies 7. PKC CP studies 8. PI3Kinase program for CP and OTM studies 9. AUY922A OTM study level activities IB updates, French HA questions |
| 2011 | CP, OTM, OBBI, DRP, TKI | CP:   1. SOM230B and SOM230C 2. LBH589X2101 and 2105 CSRs 3. TKI258A and AMN107C studies 4. PI3K CP studies   DRP:   1. Validation of Patient Profiles for SOM studies. A lot of inputs to improve the quality of overall PPs: PKC412D2201, ICL670A2209, TKI258A2302 PPs 2. Data review process in 2nd interim analysis by providing data differences for SOM studies. 3. Protocol deviations for Femara, EPO, TKI, BKM 4. Programming for DVC reports   OTM:   1. Key contributions to mono and combination studies started on PI3K, POC for MEK on-going. 2. Contributions on LDE OTM studies for IB updates, CSRs started.   Contributions on priority projects for various deliverables:   1. Analyses on PI3K studies for IB, ASCO, Internal meetings, CSR completion 2. Major contributions in PKQT, Liver toxicity analysis for PI3K and AUY projects. 3. AUY922A studies major contributions to RAP as well as study deliverables 4. LDE, BHQ, LEE IB updates   OBBI:   1. Standard M8 creation, sample codes for analysis datasets and TLFs on-going. 2. FDG PET cross project imaging analysis 3. RAF ASCO publication supported 4. Gene signature analysis on LDE 5. Special listing of interest created for RAD studies pNET study (2324) 6. RTPCR analysis for AMN/STI studies to validate the threshold value   TKI contributions:   1. 2102 CSR completed, 2. 2105 PK analysis completed, 3. 2107 on-going, 4. 2202 on-going, 5. 2201 stage I analysis and stage II analysis completed and other analysis on-going, ASCO analysis, FDA questions, PMB questions 6. IB update for 13 studies pooled together   PK QT, Liver toxicity analysis, |
| 2012 | CP, OTM, DRP, TKI | CP studies:   1. Exjade -- FDA questions, Health Canada question, CSRs, new formulation vs. FMIs –[lead] 2. SOM submission – [co-lead] 3. AMN107C2118, 2131 – CSR –[lead] 4. TKI258A2112, 2116 CSRs ongoing –[co-lead] 5. LDE225A2114 -- interim analysis –[lead] 6. RAD001X2110 – Dry run –[lead] 7. PKC – 4 CSRs –[co-lead]   OTM projects:   1. BEZ various deliverables on CSRs, IB updates, ASCO, AE risk analysis (liver toxicity, rash, asthenia, glycemia) 2. BKM – mono and combination studies 3. BYL IB update, AACR 4. HCD122A 5. BHQ880 – FIR, CSR ongoing 6. LDE225A2101 – CSR, ASCO 7. LDK378 – IB, ASCO 8. LCL161 -- IB 9. AUY – CSR up date   TKI various studies:   1. FDA commitment, 2. study CSRs ongoing 2107, 2201, 2204, 3. ongoing ECG analysis, 4. 2302 study DMC support, 5. DSUR   DRP group:   1. Various requests from NovDD studies 2. NCDS level 1 reports getting programmed, Level 2 and Level 3 awaiting the specifications from DMs |
| 2013 | OTM, DRP, LSH, LDE,LDK | OTM projects (almost all are similar to the 2012 deliverables):   1. BEZ various deliverables on CSRs, IB updates, ASCO, AE risk analysis (liver toxicity, rash, asthenia, glycemia) 2. BKM – mono and combination studies 3. BYL IB update, AACR 4. HCD122A 5. BHQ880 – CSR ongoing 6. LDE225A2101 – CSR, ASCO 7. LDK378 – IB, ASCO 8. LCL161 -- IB 9. AUY – CSR up date   DRP group:   1. Various requests from NovDD and NCDS studies on Patient profiles and exception reports 2. Data mapping from legacy standards for a CALGB study and SOM patient profiles for FDA request, Exjade listings for the DBLs 3. Jreview reports project for Data review listings -- priority 1 reports getting programmed, priority 2 and priority 3 to be completed in this year. 4. A joint project along with DMs and Clinicians on clinical review reports and patient profile updates   LSH group:   1. Contributions to various TKI, Pi3K, LDK, LDE DMCs, IB updates, DBLs approximately 25 milestones. 2. Resource augmentation of 10 LSPs from Cognizant   LDE: got involved in firefighting mode on the submission study, initially 2 programmers but then that number went up to 10 programmers. Led the Safety section of reports, as well as SCS and RMP reporting.  LDK: supported output review to help speed the NDA for LDK, programmed couple of graphs for the same. Helped correct the output for survival analysis which the study stat had also missed. The team awarded local A&B award for the support. |
| 2014 | DRP, LSH, LDE, BKM, Standards team | LDE group [led a team of 10 programmers and the following programming activities]:   1. PK CK analysis [pooled analysis] 2. PK QT analysis [pooled analysis] 3. Adjudication analysis for rhabdomylosis [pooling of 9 studies] 4. Contributions to the pivotal study 2201 5. Contributions to the DCF activities on the pivotal study 6. SCS for submissions to EU, Swiss medic and Canada so far 7. CRT creation for FDA submission 8. OSI listings for the FDA on pivotal study 9. 120 day safety updates are ongoing 10. Contributions to 3 other studies 11. 2 DMCs on individual studies 12. Set-up study team meetings with the statisticians and programmers across sites [this was a missing piece in the team]   LSH group:   1. As a team we have supported 35 different milestones across projects in the first half of the year 2014. The details are provided below 2. Dose escalation TC / snapshots = 9 3. DMCs = 5 4. Interim analysis = 13 5. DBLs = 8 6. Contributions to almost all the NCDS projects e.g. TKI, Pi3K, LDK, LDE, MEK, CTL 7. Hiring and training of resources to get the stable team [2 new associates joined the team Q1 2014] 8. Team contribution to various automation initiatives, 9. Contributions to the SOP revisions, 10. Collaboration with Genmeds on common practices.   SPS group:   1. Contributions to the TFL calling macros [Raj / Naveen] 2. Contributions to the testing of TFL macros [Naveen] 3. Validation / testing of SYSTool : dataset compare 4. Training sessions for other programmers in HYD [2 times so far this year] 5. Naveen and Rajkumar were loaded to various projects in crunch times to complete the pending tasks:    1. LDK DMCs,    2. LDE submission activities,    3. AUY DMC,    4. TKI study completion 6. After joining the group as a coordinator:   -- Worked on the OSO reviews  -- Discussions on the OSO website and contents [ongoing process]  -- RECIST 1.1 understanding of what do we have, implementation on the studies, documentation and what are the short comings [ongoing] |
| 2015 | LDE, BKM, Standards team | 1. RECIST 1.1 training slides, 2. Almost 15 studies set-up across projects. 3. SDG approach proposed for the drug grouping 4. TFL release 2.0 ongoing 5. Collaboration with Genmeds on the TFL 6. eCRS 7. Data anonymization |