

# **Annual Performance Review**

Year 2013

Name of Associate		Vinay Mahajan	Employee Number	10322				
Present Position		Group Head Since J						
Division		Pharmaceuticals	Country	India				
Business Unit/ Department		Oncology /Development						
Name of Manager	nager Andy Chopra							
Position	CDRR I	Unit head, US CDRR site head						
Name of Next Level Manager	Michael	Murawsky						
Position	Head: (	Oncology Development Operations India						
Name of Indirect Manager/Key User	Mahesh	Iyer						
Company								
Position	Head: B	iometrics, India						



# **Annual Performance Review**

# **Objectives**

Year 2013

Associate	Vinay Mahajan	Manager	Andy Chopra	Department
Position	Group Head	Position	CDRR Unit head, US CDRR site head	Oncology Development

OBJECTIVES	Evaluation Criteria; Measure-ments/Perf. Standards	Date	Priority No. / %	Self-Appraisal with Rating*		Manager Appraisal with Rating*	
Advance & individualize the pipeline	Ensure appropriate Biometrics support for the following key filings and regulatory approvals (if data supports). The support will ensure high quality and standards that none of the listed filings or approvals will be delayed due to BDM data quality or analyses.  Ensure CDRR (DR) support as appropriate:  - Contribute towards the optimization of data review and cleanup by actively participating and contributing to the Data Review Reports Project. All contributions will be of high quality and as per agreed timelines  - DR produces standard reports (statistical -SR- and data - 3 types of DR reports provided for NovDD & NCDS data) for any filings (if data supports) and regulatory approvals.  DR to produce the 3 types of DR reports provided for NovDD & NCDS data. For NovDD (Legacy) and NCDS studies on ongoing and new projects:  - Exception / DM reports (DV&C, ad-hoc, etc.) Global reports (4 / person)  - Patient Profiles (6 patient profiles / person)  - Protocol Deviation (2-3 studies)	31- Dec- 2013	60 %	The following projects have been supported by various teams. Different roles were performed across groups ranging from Support programmers, Trial and lead programmers at study level, lead programmers at a project level. DR Programming group performed almost all the activities expected out of them from different types of deliverables.  DR group:  • Various requests from NovDD and NCDS studies on Patient profiles and exception reports  • Data mapping from legacy standards for a CALGB study and SOM patient profiles for FDA request, Exjade listings for the DBLs  • Jreview reports project for Data review listings priority 1 reports getting programmed, priority 2 and priority 3 to be completed in this year.  • A joint project along with DMs and Clinicians on	2	After the transition of DRP group to Samar, Vinay has helped multiple projects. He has been instrumental in getting LDE deliverables back on time with good quality. He has been coordinating the India team very efficiently and has been a point man in the overall project team. Only with Vinay's coordination and hands on programming LDE was able to deliver on time. He continues to support LDE. He has done a great job of managing LSH team in India. He has helped hire 2 new resources in India in replacement of Ravi Suraneni and for replacement of Surender B. With the consistent coaching of Vinay, Praveen is finally stepping up and becoming an independent voice in the LSH team. Vinay has also gone out on a limb and made a case for Parul and	2

# Ensure CDRR (LSH) support as appropriate:

- LSH programmers contribute to the teams in a timely manner
- Ensure the pre-conformance, conformance, post-conformance, 3<sup>rd</sup> party load, DTS review steps are followed to make the data available
- Ensure required resources are hired, trained and functional for business continuity

#### **Ensure CDRR (SR) support for:**

- Review and comment VAP, DB specifications, CRF prior to the FPFV (when available)
- Review of RAPs: M3, M6 (within 90 days after FPFV), other RAP modules within 6 months of FPFV
- Draft RAP M8 within the 2 weeks of the RAP M7
- Provide SR support for the completion of FIR, Dry run and CSRs for the OTM as per plan
- Fully support the publications such as IB, ASCO, ASH, SABCS and decision making meetings such as TRTD (Translational Research and Translational Development board), DLT (Decision Leadership Team), and PMB (Portfolio Management Board).
- Support the transition of SR activities from OTM to OGD for compounds moving to full development

Ensure CDRR support through various sub teams (OTM, DR) to key filings, new molecules

#### Key filings:

- SOM230 in Acromegaly
- Exiade in NTDT
- Glivec / Tasigna in various submissions

clinical review reports and patient profile updates

### LSH group:

- Contributions to various TKI, Pi3K, LDK, LDE DMCs, IB updates, DBLs
- Resource augmentation of 10 LSPs from Cognizant

#### OTM projects:

- BEZ various deliverables on CSRs, IB updates, ASCO, AE risk analysis (liver toxicity, rash, asthenia, glycemia)
- BKM mono and combination studies
- BYL IB update, AACR
- HCD122A
- BHQ880 CSR ongoing
- LDE225A2101 CSR, ASCO
- LDK378 IB. ASCO
- LCL161 -- IB
- AUY CSR up date

Kumar's promotion which clearly demonstrate his enterprise level thinking and global approach. I strongly believe Vinay has a great potential and with time and direction he can be further developed.

Prior to transition of DRP to Samar, Vinay did best he could with the team he had. He had a team which did not have a whole lot of experience in J Review. In absence of good J Review skills in the DRP team it was indeed tough to manage standard reporting project. Vinay had to resort to hands on programming most of the standard reports in SAS. Even after not having right resources Vinay showed remarkable resilience in getting the reports delivered on time.

Eurthor	- TKI - Afinitor - LDK - MEK  Ensure CDRR OTM support for: Ensure optimum support and/or operational manager roles, lead roles from CDRR Hyd for OTM to plan - PI3K program, LGX818X, LGK974X, LGH447X - MEK162X - LDE225, BHQ880A - LCL161A, LDK378, INC280 - AUY922A, BGJ398X	21	2097				
Further strengthen Operational excellence	Contribute to Oncology End to End ADVANCE process resolution team as appropriate  - Ensure relevant CDRR associates attend all required ADVANCE training;  - Support for training of SOPs, BGs, various processes and methodologies within BDM;  - Collaborate to streamline BDM alignment across three operational sites: US, Basel and India by ensuring that CDRR colleagues worldwide adhere to a common programming practice and utilize standard codes from common macro libraries.  Improve the use of standards within across all projects:  - STL, standard Oncology TFL, - RECIST (if applicable to DRP), - Common DRP & SR code  Strengthen DRP Role and responsibilities:  - Establish standard libraries/catalog of NovDD and NCDS Data Review Reports and communicate it to CTT.  - Communicate libraries/catalog to CTT	31- Dec- 2013	20%	Contributions to the ADVANCE trainings by actively participating and providing inputs to the training material. Providing the associates the opportunity to attend these trainings.  Through various formal and informal team meetings building awareness about the SOPs and BGs related to BDM.  Added 10 LSP resources to the team and arranged class room trainings. Played a vital role in coordinating trainings conducted by Kumar and Surender. These resources are live on projects and have helped on NCDS projects from a resource point of view. New team structure is put in place by having people aligned by project. Parul manages the resource assignment with Kumar leading the coordination activities. Surender is	2	LSH team is stable in India currently and that's partly due to Vinay's adroit handling of FSPs and his vision. He has worked hard with Praveen to ensure that all resources have access to the right tools and applications. He had to manage the turnovers in FSP resources which he did very efficiently by hiring and interviewing the right resources and then managing the on boarding and training of right resources and helping them seamlessly transition into LSH team.  All the required training have been completed and all resources are fully compliant on SOPs and BGs.  Vinay took over the LDE project in-between and provided great leadership and	2

Contribute as appropriate to drive the following aspects on standardization and process improvement:

- No further Oncology standards would be created without consulting the Standard Outputs and Programming Governance Board.
- All requests for deviating from the standards will have to be submitted to the SR Unit Manager of the clinical program and written justification provided to the Governance Board to get approval.
- Any modification in the existing Standard Programs would have to be approved by the governance.
- The governance role will ensure consistency within Oncology and compliance to regulatory.
- The governance role will ensure implementation in NovDD and consistency in NCDS
- Ensure completion of or inputs to VAPs, RAPs, CSR's early and on time

Global operational excellence:

 Continue support developing a global operating model within CDRR as needed – managers and associates located in Tokyo, HYD, US, Basel, and Japan

#### Quality

Drive Quality mindset and increase compliance across groups within groups in Hyd.

Implement critical quality metrics for CDRR and Bios.

Ensure compliance of all training in GCPs and SOPs.

coordinating the trainings and daily activities.

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.

Supported development of RECIST macro via DR team, CRT tool via a super user role (Jayachand) as well as some teams within CP team using on the real studies.

Supported development of DR reports for NCDS studies through DR team.

The quality of the deliverables has been maintained at the accepted levels across different teams. There have not been instances of CDRR holding up timelines for lack of quality.

Participated in various global meetings.

guidance to existing team in India. He has also worked very closely with the standards team to ensure all the available standard templates are being used in developing the TLFs and ADaM datasets. LDE being the first project which is fully utilizing NCDS standards has benefitted immensely by Vinay's ongoing shepherding and leadership.

Additionally Vinay has been guiding the OTM team in India and is providing good guidance to resources.

Vinay's keen eye and insistence on providing quality deliverable is a tremendous asset for CDRR global team and it has to be utilized carefully and appropriately for further development of NCDS standards and quality team in India.

	Ensure compliance of QCSP initiative by ensuring participation  Health Authority Inspections: Implement inspection readiness, training and mock inspections/internal compliance checks across all groups.  Quality Compliance and Sustainability Program: Support implementation of key actions relevant to Biometrics.  Expand the training and compliance function in Hyd. Hire, onboard additional resource (CDRR), ensure close partnership with global counterparts to support compliance and quality initiatives.						
People/ org / culture / team	People: Hire, develop, train and retain our people Hire to plan for Hyd Biometrics.  - Focus on hiring senior staff in CDRR.  - Ensure high quality hiring, diversity and compliance to staffing processes.  Participate in 2013 Global Employee Survey (GES) and encourage the associates to participate.  Ensure that all employees have a development plan, do a TMS pulse check to support this goal, including manager's response >90% compliance.  Strengthen and build Hyd leadership pipeline and skills through targeted development, leadership programs, coaching and mentorship.  Succession plans in place for managers and key roles by supporting sustainable structure in CDRR Hyderabad.  Further develop and expand the skills of	31- Dec- 2013	15%	Strategic discussions about the possibilities of structure of SPS group, roles within DRP.  Active participation in the SPS forum, in knowledge sharing sessions. Supported Func.E initiative  Coaching and mentoring is continuously on-going for junior programmers.  Lead programmer, trial programmer roles are made available to people who are showing the required capacity via continuous dialogue with colleagues in Basel and FP.  Active reading of scientific literature and attempts to write some papers by collaborating with others  Discussions about FIRs, reports	2	Vinay is a good leader and developing into a strategic thinker and he brings a tremendous value to CDRR His skills and talents can be further utilized to make CDRR a premier organization. He is an excellent coach, mentor and great role model for resources in Hyderabad. Time and again he has demonstrated his versatility in being a PP if required or TP or an efficient hands on programmers as required. He has modified his role as required to get the job done and as such can be relied upon in getting any job done if required by CDRR organization. He has worked very closely with me in	2

	staff in Biometrics through robust on boarding (all new associates have an on boarding plan), mentoring, training in accordance with the India 2015 strategy and roadmap for Biometrics.  Retention: Retention at 95% of 3.2/2.3/3.3, maintain a low turnover rate among 2.2. Target overall regrettable turnover rate < 10%.  Drive Scientific Excellence: CDRR – innovative SAS macros, functions, presentations at SAS conferences Outside – Scientific Brand building			prepared for external presentations, interpretation of data for programmers, graphical representation, etc. routinely take place in various team meetings to increase the awareness of group.  Presentations in external conferences are continued.		developing a strategic vision for LSH and DRP and has always contributed to any plans I have discussed with him. He strives to stay aligned with me and with larger organizational goals which in itself a great quality. He has been a keen contributor to calibration process and his input is not only greatly valued but also respected across organization.	
Meet growth & profitability targets	Support Biometrics to contribute in achieving productivity targets within OGD&GMA of \$62M in 2013.  Support the global outsourcing strategy for CDRR (DR programming group, LSH group)  Support implementation and track Biometrics productivity, KPI Metrics and address improvement areas for teams based in Hyderabad.	31- Dec- 2013	5%	Participated in the identification process for choosing the FSP vendors in India and actual work getting delivered via FSP programmers.  Metrics creation is an area, which has not been worked on till now.	2	Based on my interaction with Mahesh, Vinay has been one of the key leaders of CDRR organization in India and has served as Mahesh's deputy in his absence. By all accounts Vinay is ready for any challenge posed to him.	2

Objectives discusse	d and agreed on	Date	Appraisal discussed and agreed on		d agreed on Mid-Year date: Year-End date:		Overal	Rating	
Associate			Associate				1 🗆	<mark>2□</mark>	3 □
Manager			Manager				1 🗆	2 🗆	3 🗆
Ind. Manager/			Ind. Manager/				1 🗆	2 🗆	3 □
Key User			Key User						

\* 1 = Partially met expectations 2 = Fully met expectations 3 = Exceeded expectations



# **Performance Review: Values and Behaviors**

Year

2013

Name of Associate	Vinay Mahajan	Name of Manager	Mahesh Iyer
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Novartis Values & Behaviors	Self-Appraisal with Rating* Comments (specific examples)	Manager Appraisal with Rating* Comments (specific examples)
Result driven	The team has done a great job in meeting the timelines with good quality. There has not been any instance where there was any delay due to our inability to deliver on time.  In case of LSH and DRP, we are seeing improved performance as the year progresses.  The day to day activities on projects have been managed by associates themselves, which is heading in the right direction with respect to the development of the group. DR group still needs more thinking power to move ahead strategically and lack resources do not help at all in managing the time.  LSH group is getting stable now, but we are still facing problems due to changes in the data standards which affects our ability to deliver consistently	Vinay is result oriented and clearly driven by delivering on time. He has demonstrated it on number of different occasions. In the standard reporting projects, he jumped into programming most of the reports himself as he did not have the right team. Same aspect was again evident in his support to LDK and LDE projects.

Customer/Quality Focus	2	-	Along with me all the associates have taken on themselves to think about the big picture and translating it into better quality and customer focus.  This sort of an attitude is still lacking within some of the DRP associates. Some of them have not been exposed to SR type of a job profile and may not understand the details of what to look at while thinking about quality  On DRP patient profiles, we have given a lot of comments to improve the overall quality of the deliverables. Similarly RAP reviews for various deliverables in TKI.	3	Vinay is clearly driven by quality and has discussed his concerns on number of occasions with me. He has all along been vocal and highly demanding of his team to deliver quality. I do concur with Vinay about the issues in DRP organization which needs to be staffed appropriately. Vinay worked with what he had and did his best. He took it upon himself to program the standard reports when he could not get adequate help from his team.
Innovative and Creative	2	-	Creative ways implemented while training the team to explain work related aspects. Solutions provided for re-organizing the DR group, 3d view for Biometrics development as per roadmap. Inputs into various walk-through related presentations. This is an area could be a development area for most of the DRP and LSH associates, a lot of times we are delivering what is needed but are not thinking about problems at hand. Need more thinking to help the whole team to generate more ideas.	2	Both the LSH and DRP teams need to think outside the box and come up with creative ways and processes to improve the way we work. This is one area which still needs to be the key focus of Vinay.
Competent	2	-	With increasing exposure to people management, I have developed ways to manage people.  I have improved my abilities to answer queries from local teams (on technical as well as on people front) so that minimum support is taken from Global teams.  Whenever there are questions which are unsolved, there are multiple solutions proposed.  This will continue to be an area for development for me.	2	Vinay is a competent manager. Even though both the teams under him were not appropriately staffed, he still managed to get work done on time. While Vinay's competence at the technical level has been clearly evident, there are leadership aspects which were also part of Vinay's role which I believe should be his ongoing focus as an area for further development.

Leadership	2	yı te - I ri ri ta - Lı a	think I have improved as a leader over the ears. I am more comfortable in leading a eam and guiding the team as a leader. think I am guiding the team towards the ight direction to take on more complex asks.  eading a team globally is new to me but I m taking steps in the right direction by ontinuously talking to other seniors.	2	Vinay needs to continue developing as a global leader. I will work with him further to develop his potential.
Fast/Action-Orientation/Initiative/Simplicity	2	- I and the second of the seco	have kept myself away from day to day ctivities at each project level. I have given hat responsibility to each individual to take eccessary decisions with continuous upport. In return the team has responded ery well.  have given my team the required amount of responsibility to handle their project and have made them accountable for the same.	2	While Vinay does takes on tremendous initiative and is quite speedy with his deliverables. Moving forward, I will continue to work closely with Vinay on further development.
Empowerment/Accountability	2	fu - T to to is S g ir ir	am committed to developing associates urther to take on more responsibilities. This year, I have given more responsibilities to the senior programmers within the team to develop the junior associates. OTM team is functioning well under Murali and Priya. Shiva has done a good job with FSPs on DR group. Satya has really shown in taking more responsibility in the jreview project on programming side with me.	2	Vinay has tried best to develop his team with the constraints he had. He has succeeded in building a good structure in both DRP and LSH. He does empower his associates and encourages them to take good decisions.
Commitment/Self-discipline	2	- I:	am committed to developing associates nd developing teams with new structure urther to take on more responsibilities.	3	Vinay is very committed to success of CDRR and Novartis. His commitment is evident by his eagerness to jump into any project which requires his help as his contributions have been widely recognized in LDK and LDE.

Mutual Respect/Candor/Trust/Integrity/Loyalty	2	- I have communicated timely in a consistent manner. I have been open to the criticism on the shortcomings.  2 Vinay is well respected in the organization. He laways shown respect to his peers and has bee reciprocated in return.	
Open Communication/Collaboration/Compassion	2	<ul> <li>I have trusted the team to the possible extent. I have been accountable for my own mistakes.</li> <li>One of the examples could be related to the reality check on the DR group and LSH group. To my mind, how we are set-up as a group is faulty. At least the DRP group should be more aligned with the rest of the programming teams across different proejcts.</li> </ul> Vinay's communication is very open and collaborative.	

<sup>\* 1 =</sup> partially met 2 = fully met 3 = exceeded

Overall Self Appraisal (Rating)\*

2

Overall Manager Appraisal (Rating)\*

#### **Novartis Values & Behaviors**

#### Results driven

- Can be relied upon to exceed targets successfully
- Does better than competition
- Pushes self & others for results while staying in bounds of ethical and legal
   standards

## **Customer / Quality Focus**

- Assigns highest priority to customer satisfaction
- Listens to customer & creates solutions for unmet customer needs
- Establishes effective relationships with customers and gains their trust & respect

#### **Innovative & Creative**

- Comes up with a lot of new & unique ideas
- Challenges "status-quo": does not settle for the first right idea
- Makes new connection work by seeing relationships between seemingly

# **Empowerment/Accountability**

- Sets clear performance targets and a well defined "playing-field" with corresponding personal accountability
- Defines clear-cut, flexible involvement process (involves the right associates in the right situation at the right time)
- Fully utilizes diversity of team-members to achieve superior business success
- Shares consequences of results with all involved
- Fully cooperates with all organizational compliance initiatives and legal requests, as well as motivates others to behave in a way that ensures adherence to the same

## Commitment/Self-discipline

- Fully supports and implements decisions
- Is 100% committed to achieve agreed-upon targets (strives to achieve the

disconnected elements, synthesizes odd combinations

#### Competent

 Has functional & technical knowledge & skills to successfully perform his/her role

#### Leadership

- Establishes clear directions and sets stretch objectives
- Aligns and energizes associates behind common objectives
- Champions the Novartis Values & Behaviors. Rewards/encourages the right behaviors and corrects others

#### Fast/Action-oriented/Initiative/Simplicity

- Is action-oriented & full of energy to face challenging situations
- Is decisive, seizes opportunities and ensures fast implementation
- Strives for simplicity & clarity. Avoids "bureaucracy"

"slightly impossible")

 Pursues targets with a need to finish. Does not give up, especially in the face of adversity

### Mutual Respect/Candor/Trust/Integrity/Loyalty

- Establishes mutual respect and trust in dealing with others
- Acts and behaves in accordance with his/her words
- Commits to honesty/truth in every facet of behavior and demonstrates ethical and legal conduct
- Keeps confidences, admits mistakes & does not misrepresent self for personal gain

### Open Communication/Collaboration/Compassion

- Communicates in open, clear, complete, timely, and consistent manner
- Listens effectively and invites response
- Genuinely cares for people & demonstrates empathy
- Is a team player



## **Annual Performance Review - Manager**

Year 2013

Name:	Andy Chopra	Position:	CDRR Unit head, US CDRR site head
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## **Overall Performance Evaluation**

CTIVES	3 Exceeded expectations	SUPERIOR RESULTS, UNSATISFACTORY BEHAVIORS 3.1	SUPERIOR RESULTS, GOOD BEHAVIORS 3.2	SUPERIOR RESULTS, SUPERIOR BEHAVIORS 3.3
	2 Fully met expectations	GOOD RESULTS, UNSATISFACTORY BEHAVIORS 2.1	GOOD RESULTS, GOOD BEHAVIORS 2.2	GOOD RESULTS, SUPERIOR BEHAVIORS 2.3
OBJE	1 Partially met expectations	UNSATISFACTORY RESULTS, UNSATISFACTORY BEHAVIORS 1.1	UNSATISFACTORY RESULTS,  GOOD BEHAVIORS  1.2	UNSATISFACTORY RESULTS, SUPERIOR BEHAVIORS 1.3
_		1 Partially met expectations	2 Fully met expectations	3 Exceeded expectations

#### NOVARTIS VALUES & BEHAVIORS

### **Performance Summary**

Overall this has been a challenging year for Vinay, in spite of facing numerous issues; he managed his teams pretty well. With all the potential, commitment and dedication he has I am sure he will continue to be very productive for CDRR and Novartis in the years to come.

### Key Strengths (current and future assignments)

His loyalty, commitment, quality focus and his dedication remains his key strengths.

## **Key Developmental Needs (current and future assignments)**

He will continue to focus on global leadership development skills.

#### **Associates Comments**

No comments to add.

Date	Signed Associate*	
Date	Signed Manager	
Date	Signed Next Level Manager	

<sup>\*</sup> Signature by Associate does not necessarily indicate agreement, only review and notification.



If need be, use a blank sheet of paper for additional comments on the appraisal.



## Annual Performance Review - Indirect Manager/Key User

Year 2013

Name: Mahesh Iyer Position: Head: Biometrics, India

## **Recommended Performance Evaluation**

OBJECTIVES	3 Exceeded expectations	SUPERIOR RESULTS, UNSATISFACTORY BEHAVIORS 3.1	SUPERIOR RESULTS, GOOD BEHAVIORS 3.2	SUPERIOR RESULTS, SUPERIOR BEHAVIORS 3.3	
	2 Fully met expectations	GOOD RESULTS, UNSATISFACTORY BEHAVIORS 2.1	GOOD RESULTS, GOOD BEHAVIORS 2.2	GOOD RESULTS, SUPERIOR BEHAVIORS 2.3	
	<b>1</b> Partially met expectations	UNSATISFACTORY RESULTS, UNSATISFACTORY BEHAVIORS 1.1	UNSATISFACTORY RESULTS,  GOOD BEHAVIORS  1.2	Unsatisfactory Results, Superior Behaviors 1.3	
		<b>1</b> Partially met expectations	<b>2</b> Fully met expectations	3 Exceeded expectations	
NOVARTIS VALUES & BEHAVIORS					

### Comments

Date Indirect Manager/Key User