DM365

Data Management

DM365
Helpdesk and Analytics

November 2017

EDC & IWRS Helpdesk

- Involved staff
  - Helpdesk specialist
  - Head of Analytics
- Requests reception
  - Phone
  - Email
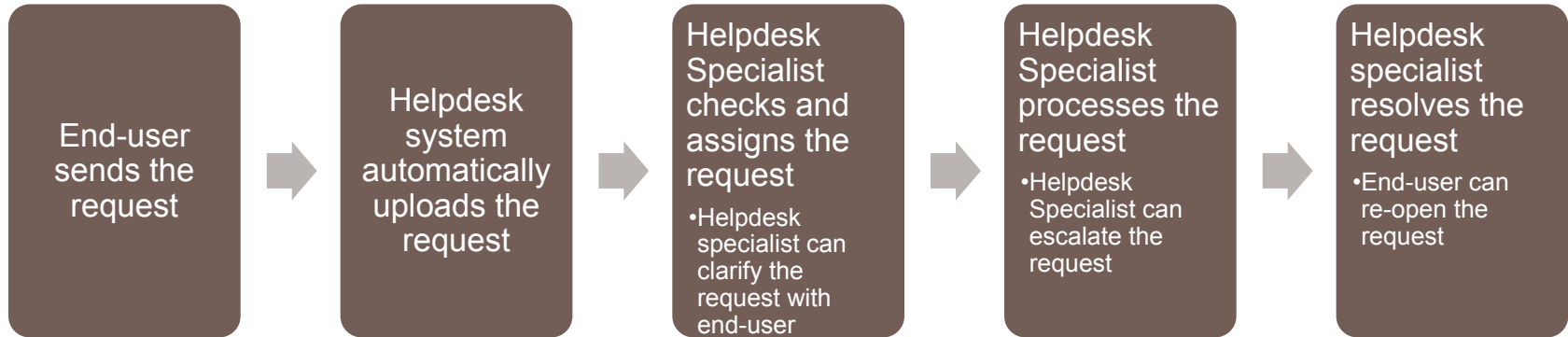 - Helpdesk ticketing system
- Helpdesk is UNBLINDED!

EDC & IWRS Helpdesk

- Working hours
  - Russian Federation, from 10.00 till 18.00 Moscow time on business days
  - emergency phone calls 24x7 for Business Impact issues
- Response time

Issue impact level	Maximum time to acknowledge a query	Maximum time to resolve Issue
Business Impact	30 minutes	8 hours
Group Impact	12 hours	72 hours
User Impact	24 hours	7 days

Process

End-user sends the request	Helpdesk system automatically uploads the request	Helpdesk Specialist checks and assigns the request •Helpdesk specialist can clarify the request with end-user	Helpdesk Specialist processes the request •Helpdesk Specialist can escalate the request	Helpdesk specialist resolves the request •End-user can re-open the request

Helpdesk

Helpdesk activities

- Access granting/revoking
- Data Change Requests processing
- IWRS support
- User consultancy

Emergency situations

- Promptly informs Helpdesk System provider that Helpdesk System is down
- Helpdesk personnel processes requests via corporate mail service (email)
- Incoming emails are automatically processed by Helpdesk System after system recovery
- If the Internet connection is down, Helpdesk personnel processes requests by phone

Analytics – general activities

- System change process - development, review and approval of requirements specifications
- Validation - development of requirements specifications
- User access control - development, review and approval of requirements specifications related to Client-specific needs
- Helpdesk – 2nd level of support

Analytics – IWRS Development

- Inputs
  - Study Protocol
  - eCRF Design Specification (pre-final)
  - Study Database Specification (pre-final)
- Actions
  - Requirements gathering and elicitation
  - IWRS CRS development and approval
  - IWRS completion guidelines and approval