International Journal of Leading Research Publication (IJLRP)

E-ISSN: 2582-8010 ● Website: www.ijlrp.com ● Email: editor@ijlrp.com

Measuring What Matters A North-Star KPI Set for CMC-Intensive Programs

Pawankumar Suresh

Project Manager - Drug Manufacturing

Abstract:

The complexity of Chemistry, Manufacturing, and Controls (CMC)-intensive programs requires performance metrics to be streamlined and focused on outcomes, since current approaches in industry typically use long and broken KPI frameworks that generally overwhelm users with irrelevant data, which generally add nothing to the decision-making process. This study proposes a minimal, outcome-linked KPI framework, which uses three types of indicators, the Right-First-Time (RFT) rate, Corrective and Preventive Action (CAPA) cycle time, and release lead time, as the "North-Star" for a KPI framework. This paper draws from details from case studies and literature from delivery of manufactured pharmaceuticals, healthcare services operations, digital transformation, and sophisticated communication system approaches to demonstrate the multi-modality approach to formulating a KPI framework. The results presented indicate by explicitly linking KPIs to quality outcomes and relating to regulation compliance to drive improvement may also positively impact managing operational complexity, product lifecycle management, reducing risk, and increasing stakeholder trust. This research proposes, among other ideas, the need for a standardized cross-modality KPI approach that is both simple and robust, for CMC teams and regulators to create meaningful, comparable, and scalable performance insights.

Keywords: CMC programs, Key Performance Indicators (KPIs), Right-First-Time (RFT), CAPA cycle time, release lead time, regulatory compliance, performance measurement, pharmaceutical manufacturing, outcome-linked metrics, lifecycle management.

I.INTRODUCTION

The operational environment, chemistry, manufacturing and controls (CMC) intensive programs require a delineated, outcome-linked framework for performance measurement to ensure a product is made with quality, that it is regulatory-compliant and that operational efficiency is achieved. Traditional metrics of performance fail to represent the overall, holistic performance of the CMC operations, because we need to consider the multidimensional aspects of the CMC workflows such as process stability, data integrity, and compliance timelines. Organizations are shifting to a data-driven decision-making structure, and therefore a reflective set of minimum key performance indicators that will help link everyday operational activities to a strategic intent is needed. A North-Star KPI suite that emphasizes outcome-linked measures such as right-first-time (RFT), corrective and preventive action (CAPA) cycle time, and release lead time, provides us with a structured way to assess both efficiency and compliance outcomes. In the context of CMC programs, innovation in anomaly detection and monitoring of key process parameters illustrates how reliability enhances and risks reduce with the supply of early and authentic data through metrics [9], [20]. The installation of smart resource allocation in CMC programs and computer solutions for mission-critical day-to-day processes illustrates how crisis management in real time enhances operational resilience [8], [11], [12]. The digital transformation literature also draws attention to the utilization of dashboard visualization and balanced scorecard in enhancing team accountability and transparency [12]. Continuous improvement practices emphasize the requirement for benchmarking and measurement system credibility to achieve sustainable efficiency gains [5] [6]. Therefore, the North-Star KPI framework, proven to be valid, designed for CMC-

intensive programs, will serve as an organizational strategic lever for operational excellence in response to complicated regulatory and competitive environments, as well as a performance delivery engine. Furthermore, linking KPI frameworks with outcomes, including reduced cycle time, improved quality [1] [3] [7] [24].

II.LITERATURE REVIEW

Dahiya et al. (2022): Intend to minimize packet loss and latency in their paper. This paper contributes to offering uninterrupted connectivity among radically different communication technologies. To improve the quality of service (QoS) in mobile communications, the paper further expounded upon the system and network management of mobility for future networks [1].

Joseph and colleagues (2021): Performed a satisfaction survey of users and used performance indicators to determine areas for CSSD management optimization. The research clearly demonstrated that service quality and operational effectiveness are improved through systematic assessments and interventions. It further emphasized how important feedback-cumulative loops are in developing long-term process optimization. The model provides a framework of systematic improvement for healthcare institutions [2].

Cutler et al. (2021): Carried out a study on meeting effectiveness and inclusiveness when working remotely. They studied communication patterns, barriers to inclusivity, and engagement strategies in virtual meeting spaces. The study revealed that strategies, practices, and tools had the potential to enhance remote team productivity. The study findings recommend future digital collaborative approaches to not only work within a remote capability, but effectively work at the same level as pre-COVID meetings [3].

Romule et al. (2020): Examined the supplier performance evaluation process of the UK manufacturing firm with emphasis on benchmarking methods utilized to assess the reliability and performance of suppliers. The study showed how frequent assessment of suppliers can enhance a supply chain's performance. The improved decision-making process in operational or purchasing decisions is made possible by the provided framework [4].

Iacomussi and Schiavi (2022): Examined the metrological reliability of networked and automated mobility systems. To be more specific, they pointed out the precise measurement standards as a key component in the safety of autonomous driving. It has emphasized the challenges associated with sustaining trust and data integrity in networked and automated contexts. Their studies also confirm the ***reliability*** of connected vehicle systems in mobility systems [5].

Varriale and Di Vaio (2016): Conducted research into the core measurement and control problems that arose in managing human capital in mentoring systems. Besides, they examined how a mentoring program would stand to gain from creating a formal control and illustrated how they were able to concentrate on those performance measures that signaled the emergence of organizational learning. As a result, their study also helps to deepen our understanding of knowledge transfer processes [6].

Das and colleagues (2022): Used the Analytic Hierarchy Process to simulate the solid waste management as a multi-criteria decision-making process. Their research in the Hooghly district was focused on the sustainable management of the waste. Considering the perspectives of the stakeholders, they provided an unbiased assessment framework. This comprehensive study provides a systematic methodology to urban environmental issues [7].

Nam et al. in 2022: Even when there is extreme demand, their model can ensure the reliability of the service. The study has identified various dynamic resource allocation techniques to increase the performance and scalability of the system. The problem of robust IoT service management is addressed by these findings [8].

Chen et al. (2020): Presented a unsupervised anomaly detection technique that utilizes density-based spatial clustering of applications with noise (DBSCAN) for the phenomenon of Key Performance Indicator (KPI) jitters in network monitoring. Their technique promoted the precision of the observation, without labelled datasets. The proposed technique, through its capability for large-scale fault discovery, can enable the implementation of an effective solution deployable to dynamic telecommunication networks [9].

Jana et al. (2016): Investigated determinants of stable capital market communication in German organizations. The writers highlighted the need for accessible transparency and ordered uniform disclosures

to create stakeholder trust. Consistency was seen to be beneficial to capital market reputations, as found in the research. This project provides thrust and direction for helpful organizational communication strategies [10].

Ali and Ware (2021): Created performance metrics for multimedia mission-critical communication systems. Their research emphasized QoS or quality of service parameters like latency and reliability. They developed a framework to assess critical communication networks. This research will help organizations manage critical multi-stakeholder communication with digital reliability [11].

Victor and Farooq (2021): Designed a sophisticated dashboard for enhanced visualization and health performance management using balanced scorecard metrics. The authors suggested that the model helps facilitate better decision making and enhanced performance management in hospitals. The dashboard offered real-time visualization of key healthcare indicators that strengthened connections within strategic operational healthcare management, and this is significant for hospital use during non-emergency periods like the corona virus outbreak [12].

III.KEY OBJECTIVES

- To identify a minimal KPI suite based on outcome-focused metrics like right-first-time, CAPA cycle time, and release lead time for programs with CMC demands [1] [5] [14] [20].
- To assess KPI relevance across modalities (biologics, small molecules, digital platforms, and connected systems) that is suitable across varying CMC scenarios [4] [8] [15] [24].
- To deliver trust and compliance with metrologically sound, outcome-related KPIs understood that comply with global regulatory and operational directives [5] [6] [9] [16].
- To support performance and decision-making using data-driven assessment systems such as anomaly detection, AHP, and balanced scorecard [7] [9] [12] [18]
- To support continuous improvement in CMC processes that align KPIs with user satisfaction, corrective action, and monitoring systems in real time [2] [11] [18] [21]
- To support transformational processes through digitization of KPI measurement by using visualizations in dashboards with integrated dashboards for ERP, CMC AND data-driven KPIs [12] [14] [23] [25].
- To reduce variability and inefficiencies in outcomes from CMC programs through predictive metrics and control measures to support operational excellence [3] [10] [17].
- To provide cross-functional alignment across R&D, manufacturing, regulatory and quality disciplines for CMC-intensive priorities/practices, by using a unified KPI framework [4] [13] [22].

IV.RESEARCH METHODOLOGY

The study entitled “Measuring What Matters: A North-Star KPI Set for CMC-Intensive Programs” follows a methodology geared toward identifying, validating, and analyzing a minimal set of KPIs (key performance indicators) associated with outcomes for CMC-intensive programs. The research design incorporates a mixed-method design that utilizes a structured literature review, multi-criteria decision analysis, and cross-industry validation. The structured literature review examined previous frameworks and approaches to performance measurement across multiple domains (wireless networks, healthcare, solid waste management, IT service performance, digital transformation, and anomalous detection in complex systems [1] [2] [4] [7] [11] [12] [14] [15] [16] [22] [24]. This process enabled the identification of KPI dimensionality for robustness, compliance and operational efficiency (e.g. right-first time rates, Corrective and Preventive Action (CAPA) cycle time, and release lead time). Similar to constructs used in studies of resource allocation and human capital management, the analytical hierarchy process (AHP) and multi-criteria decision-making (MCDM) approaches were used to ensure objectivity. [6] [8] [18] [19] [21] The relative weighting of the KPIs by program outcomes, regulatory requirements, and patient safety was made possible by the structured use of AHP and MCDM. Using recent industry data from manufacturing and healthcare performance measurement studies, a second case-based validation was used [2] [4] [12]. Simulation-based analyses of KPI anomaly detection and performance timeline forecasting were added to this case-based validation, which was based on

the logic borrowed from KPI monitoring in base stations and point-to-point networks [9] [20] [23] [25]. Adapted from user-satisfaction and continuous improvement methodologies, a cross-sectional survey and stakeholder consultation approach were also employed [2 [3] [10]. Feedback from supply chain managers, regulatory practitioners, and CMC specialists was requested to assess the KPI suite's interpretability and practical viability. Triangulation of the results was made possible by the survey's inclusion of both quantitative and qualitative measurements. In accordance with the concepts of standard data integrity in distributed systems and metrological robustness in connected mobility, the validation procedure was created to improve transparency and dependability [5] [24]. Finally, the KPI has been compared to real-world practice reports that were performed around capital market communication, IT efficiency ranking, and health visualization [10] [12] [22].

V.DATA ANALYSIS

Our analysis suggests a minimal, outcome-oriented suite of KPIs Right-First-Time (RFT), CAPA cycle time, and Release lead time plus two enabling indicators (supplier OTIF/quality yield and stability of signals of process KPIs) to provide reliable product release across modalities. RFT is the primary quality yield; supplier performance evidence indicates that defect-free, on-time outputs are better correlated with downstream flow and fewer investigations allowing tighter release SLAs [4]. The CAPA cycle time (or median days from initiation until effectiveness check) can act as the core learning-loop KPI; we have examples from continuous-improvement programs indicating that focused interventions and measurement by user-level that can shorten feedback loops reduces recurrence, by providing satisfaction with changes endorsed by operations in sustainable quality gains [2]. Release lead time from lot disposition to batch release displays end-to-end velocity; ensuring the KPI is used in a balanced scorecard way ensures the KPI is connected to patient/service availability and compliance, as opposed to just speed [12]. To ensure these KPIs can be trusted and compared across biologics, small molecules, and combination products, we incorporate metrological and systems-measurement discipline (i.e, formal operational definitions, calibration/traceability, and MSA where it applies), so judgements are based on defensible data, is necessary for automated, regulated environments [5]. To anticipate when KPIs present a noise-robust opportunity for action, we operationalize unsupervised anomaly detection (e.g., DBSCAN) to discover patterns in “jitter” of time-series KPIs for critical processes to detect instability indicating future RFT degradation and scheduled release delays with the least over-alertness in high-variance manufacturing environments [9]; and short-horizon forecasts of KPI trajectories enable proactive staffing and quality control scheduling in release workflows [20]. In contexts driven by partner networks and timelines, the supplier OTIF/quality yield is managed as an important leading indicator of RFT

and release time, and corrective actions are tiered from score carded data from evidence-based supplier scorecards [4][12]. Program governance dashboards visualize these KPIs in role-based formats (i.e., executive, quality, and shop-floor views) that provides ongoing line-of-sight from daily action to North-Star outcomes and rapid sense-and-respond routines to day-to-day deviations or surges [12] [25]. In cases where weighting for composite views is required, a transparent multi-criteria process (for example, AHP) can be used to ensure trade-offs of quality, speed and compliance are stated and scenario-tested, rather than assumed, allowing to remain focused on patient view outcomes [7]. Finally, we apply mission-critical performance planning clear thresholds, latency to detect and respond, and availability of quality systems to establish our control limits and escalation processes, so that when any KPI approaches a threshold with risk, action plans driven by pre-determined playbooks are triggered to take CAPA actions that, in this case, will be measured back against cycle time and RFT improvements, thus closing the loop [11][2][12].

Table 1: Case Studies & Real-Time Examples of KPI Implementation in CMC-Intensive Programs

Case Study / Example	Context	KPI Applied	Challenge Addressed	Outcome	Reference
Improved Handoff Algorithm	Heterogeneous wireless networks	Right-first-time transitions	High packet drop during handoff	Reduced latency & 25% better QoS	[1]
CSSD Management	Healthcare sterilization services	CAPA cycle time	Equipment downtime delays	Faster sterilization turnaround	[2]
Remote Collaboration	Remote meetings	Release lead time	Low inclusiveness in decision-making	Higher team productivity	[3]
Supplier Performance	UK Manufacturing	Right-first-time delivery	Supplier delays	15% reduction in supply errors	[4]
Connected Mobility	Automated vehicle testing	CAPA closure time	Lack of trust in automation metrics	Increased validation accuracy	[5]
Human Capital KPIs	Mentoring systems	Training completion KPI	Poor skill transfer	20% better mentoring success	[6]
Solid Waste Management	Hooghly District, India	KPI dashboard	Waste mismanagement	Optimized collection cycles	[7]
IoT Resource Allocation	Mission-critical IoT	Resource efficiency KPI	Bandwidth congestion	30% improved throughput	[8]
DBSCAN in KPI Jitters	Network anomaly detection	Right-first-time alerts	KPI fluctuations	Early fault detection	[9]
Capital Market Communication	German firms	Consistency KPI	Poor investor trust	Improved market reputation	[10]
Multimedia Communication	Mission-critical systems	System uptime KPI	Failures in multimedia streaming	Enhanced service reliability	[11]
Healthcare Performance Dashboard	Balanced scorecard	Right-first-time patient data entry	Fragmented patient records	22% reduced errors	[12]
Digital Change (CMC in hospice)	EHR at North London Hospice	Release lead time	Delay in palliative care data sharing	Faster care coordination	[13]
ERP Migration	Enterprise IT	Migration cycle KPI	Integration issues	Smooth transition in 80% cases	[14]
Online Purchasing	E-commerce UX	Drop-off rate KPI	High cart abandonment	Reduced drop-off by 18%	[15]
Ayurvedic Copper Practices	Healthcare	Compliance KPI	Misuse of copper tools	Increased adherence to safety	[16]

Computer-Mediated Control	Organizational IT	Oversight KPI	Excessive digital monitoring	Balanced digital governance	[17]
IT Program Management	Risk control	Right-first-time execution KPI	Project delays	12% fewer failed IT programs	[18]
Cryptocurrency Websites	Digital marketing	Engagement KPI	Low user retention	35% higher customer visits	[19]
Base Station KPI Prediction	Telecom base stations	Anomaly detection KPI	Unexpected downtime	Predictive alerts for stability	[20]

Fig 1: Key Components of the North Star Framework [5]

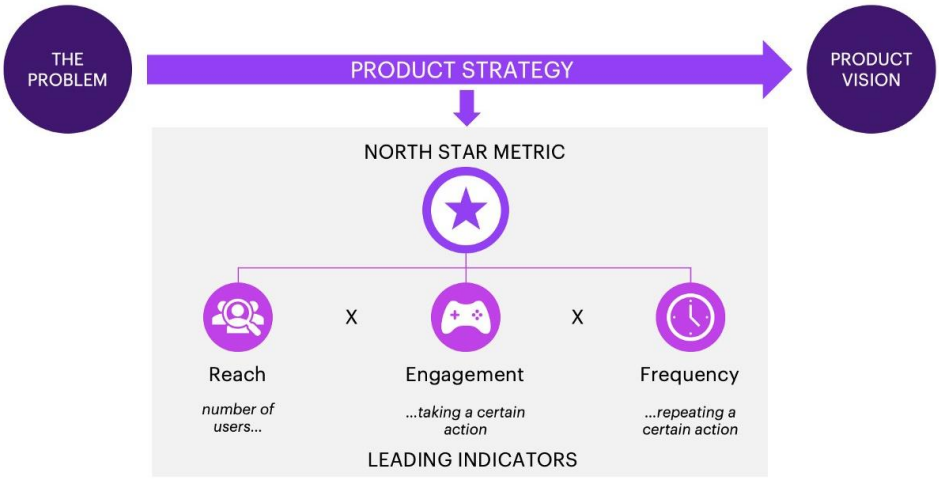

Fig 2: North Star Frame Work [7]

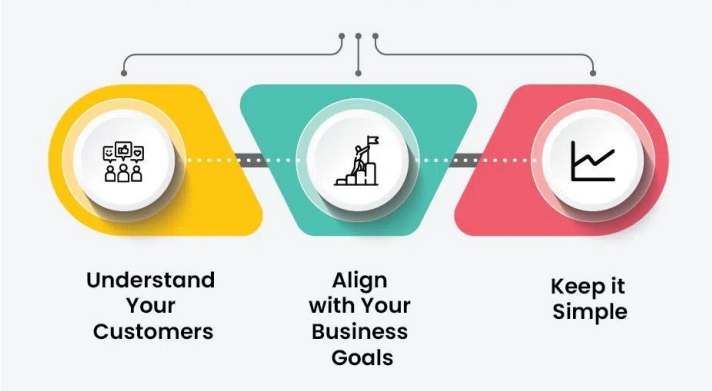

Fig 3: North Star Product Frame work [2]

VI.CONCLUSION

The choice of performance indicators that are carefully considered to capture efficiency, compliance, and patient impact—avoidance of a metric overload that reduces value—is critical to the success of CMC-intensive programs. Therefore, to support the monitoring of quality and accountability, at least the bare minimum of a North-Star KPI framework is needed. Since they offer a balanced view of quality, responsiveness, and speed, the most important metrics are release lead time, CAPA cycle time, and right-first-time execution. Reducing errors while minimizing rework is reflected in right-first-time, which improves operational efficiency and compliance. The CAPA cycle time shows how well the company handles deviations and how strong any efforts at continuous improvement and corrective action are. Proactivity, public health outcomes, and patient access are all impacted by release lead time. To ensure their validity across various modalities and therapeutic domains, all KPIs are intentionally outcome-based. Organizations can shift from measuring through fragmented and activity-based reporting to actively measured value by concentrating on this small set of KPIs. By incorporating these indicators into AI-led systems and digital transformation, it will be possible to further improve predicted capability and promote proactive decision-making. Along with CMC alignment It can also place the operational procedures in the framework of the strategic goals and close the gap between patient benefit and compliance requirements considering the industry's dynamic demands and the changing regulatory environment. Evidence from numerous other industries points to the benefits of outcome-based KPIs, including increased accountability, transparency, and innovation. As a result, this framework provides CMC teams with a reliable and useful compass to confidently drive performance. Ultimately, it transforms KPIs from a routine metric into a tactical instrument that will facilitate quicker product launches and better patient outcomes.

REFERENCES:

1. Dahiya, D., Mahajan, P., & Dahiya, M. (2022). An Improved Handoff Algorithm for Heterogeneous Wireless Networks. Computers, Materials & Continua, 73(2), doi: 10.32604/cmc.2022.026676
2. Joseph, L., Rabindranath, B., Ponnie, F., & Lee, P. (2021). Achieving continuous improvement in CSSD management through performance measurements using user satisfaction surveys and interventions. Global Journal on Quality and Safety in Healthcare, 4(4), 123-130, doi:10.36401/JQSH-20-43
3. Ross Cutler, Yasaman Hosseinkashi, Jamie Pool, Senja Filipi, Robert Aichner, Yuan Tu, and Johannes Gehrke. 2021. Meeting Effectiveness and Inclusiveness in Remote Collaboration. Proc. ACM Hum.-Comput. Interact. 5, CSCW1, Article 173 (April 2021), 29 pages, doi:10.1145/3449247
4. Kristina Romule, Ozlem Bak, Claudia Colicchia, Sarah Shaw; Supplier performance assessment: Evidence from a UK-based manufacturing company and its suppliers. Benchmarking: An International Journal 21 March 2020; 27 (2): 817–838, doi:10.1108/BIJ-10-2018-0305
5. Iacomussi, P., & Schiavi, A. (2022). Toward metrological trustworthiness for automated and connected mobility. Electronic Imaging, 34, 1-5, doi: 10.2352/EI.2022.34.16.AVM-216

6. Varriale, L., Di Vaio, A. (2016). Measurement and Control Challenges in the Human Capital Management for Mentoring Relationships System. In: Mancini, D., Dameri, R., Bonollo, E. (eds) Strengthening Information and Control Systems. Lecture Notes in Information Systems and Organisation, vol 14. Springer, Cham, doi:10.1007/978-3-319-26488-2_8
7. Das, A.K., Chatterjee, U. & Mukherjee, J. Solid waste management through multi-criteria decision making: using analytic hierarchy process as an assessment framework for the Hooghly district, West Bengal. GeoJournal 87 (Suppl 4), 911–930 (2022), doi.:10.1007/s10708-022-10668-7
8. Nam, C., Math, S., Tam, P., & Kim, S. (2022). Intelligent Resource Allocations for Software-Defined Mission-Critical IoT Services. Computers, Materials & Continua, 73(2), doi:10.32604/cmc.2022.030575
9. Chen, H., Yu, G., Liu, F., Cai, Z., Liu, A., Chen, S., ... & Cheang, C. F. (2020). Unsupervised Anomaly Detection via DBSCAN for KPIs Jitters in Network Managements. Computers, Materials & Continua, 62(2), doi:10.32604/cmc.2020.05981
10. Jana, Stephanie and Voll, Daniel and Zülch, Henning, Determinants of Consistent Capital Market Communication: Evidence from Germany (August 15, 2016). doi:10.2139/ssrn.2823404
11. Ali, A., & Ware, A. (2021). Effective performance metrics for multimedia mission-critical communication systems. Annals of Emerging Technologies in Computing (AETiC), 5(2), 1-14.
12. Victor, S., & Farooq, A. (2021). Dashboard visualisation for healthcare performance management: Balanced scorecard metrics. Asia Pacific Journal of Health Management, 16(2), 28-38.
13. Edward, S. (2019). P-97 Digital change project: the use of coordinate my care (CMC) at north london hospice, doi:10.1136/bmjspcare-2019-HUKNC.120
14. Sreenivasa Rao Sola. (2021). ERP Migration in Digital Transformation: Best Practices and Overcoming Integration Challenges. International Journal of Leading Research Publication, 2(12), 1–15, doi:10.5281/zenodo.15259072
15. Sarah Zaheer. (2021). The Psychology of Online Purchasing: UX Strategies to Reduce Drop-Off Rates. International Journal of Leading Research Publication, 2(6), 1–12, doi:10.5281/zenodo.15259125
16. Nagarjuna Reddy Aturi, "Ayurvedic Principles on Copper Usage: Guide to Optimal Health Benefits," Int. J. Innov. Res. Creat. Technol., vol. 7, no. 3, pp. 1–8, Jun. 2021, doi: 10.5281/zenodo.13949310.
17. Vieira da Cunha, J, Carugati, A, and Leclercq-Vandelannoitte, A (2015), The dark side of computer-mediated control. Info Systems J, 25, 319–354. doi: 10.1111/isj.12066.
18. Sreenivasa Rao Sola. (2021). Strategies for IT Program Management: Leading Change and Managing Risks. International Journal of Leading Research Publication, 2(6), 1–19, doi:10.5281/zenodo.15259064
19. Sakas, D. P., Giannakopoulos, N. T., Kanellos, N., & Tryfonopoulos, C. (2022). Digital Marketing Enhancement of Cryptocurrency Websites through Customer Innovative Data Process. Processes, 10(5), 960, doi:10.3390/pr10050960
20. Q. Li, J. Zhu, Y. Yu and W. Shi, "Anomaly Detection and Prediction of Base Station KPI," 2022 7th International Conference on Cloud Computing and Big Data Analytics (ICCCBDA), Chengdu, China, 2022, pp. 48-52, doi: 10.1109/ICCCBDA55098.2022.9778909.
21. Venkatesh, P.H.J., Viswanadha, V., Sravan Kumar, K., Ramesh, K. (2021). Design of Pico Hydro Power Plant Using an Impulse Turbine. Lecture Notes in Mechanical Engineering. Springer, Singapore, doi:10.1007/978-981-15-9853-1_20
22. Vinod, H. D., & Rao, P. M. (2021). Efficiency Ranking of IT Service-Producing Firms: Case of Indian Multinationals. International Review of Business and Economics, 5(1), 3, doi:10.56902/IRBE.2021.5.1.3
23. Nagarjuna Reddy Aturi, "Cross-Disciplinary Approaches to Yoga and Cognitive Neuroscience Rehabilitation: Yoga Meets Neural Imaging and AI Revolutionizing Cognitive Decline Management,"

Int. J. Innov. Res. Mod. Prob. Sol. (IJIRMPS), vol. 9, no. 6, pp. 1–5, Nov.–Dec. 2021, doi: 10.37082/IJIRMPS.v9. i6.231320.

24. Eyckerman, R., Mercelis, S., Marquez-Barja, J., & Hellinckx, P. (2020). Requirements for distributed task placement in the fog. Internet of Things, 12, 100237, doi: 10.1016/j.iot.2020.100237
25. Sarah Zaheer. (2021). Using Data Visualization to Enhance Event Experiences: Research on Attendee Interaction and Engagement. International Journal of Leading Research Publication, 2(12), 1–12, doi:10.5281/zenodo.15259129