

Research on the Positive Feedback Mode of Drug Supervision Informatization under New Institutional Reform

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Abstract: Based on the new institutional reform, medicine supervision was featured with targeting, elaborating and promptness ability. Base on the binary full life cycle analyze and the clarifying of informationized supervision construction and reformation system arrangement, this article divided food & drug informationized supervision into three elements including supervision process, informatization techniques, and data decision. Data decision tools played the technical support role in supervision performance evaluation, software verifying and upgrading. It inspected supervision and informationized binary structured positive feedback mechanism, which is the new and original idea. It also proposed informationized supervision pathway of big data assessment, precise regulation, collective intelligence, and cyber security.

Introduction

Base on the developed environment of big data, internet plus, artificial intelligence (AI), cloud algorithm and other cutting-edge techniques, manufacturing, managing and consuming area of drugs were diversified, personalized and globalized. Novel industries and modes like online drugstores, MAH (Marketing Authorization Holder), online catering cross-broader e-commerce were emerged constantly. Under new system, with faster and deeper evolution speed of drugs supervision system, occasionally supervision system reformation stagnant, “delegate power, streamline administration and optimize government services” administration reformation, “Triple novel” concepts (Novel industry, format and commerce mode), risk alarming mode and other system arrangement requirement, it was difficult to locate the increasing complicated market subject supervision risk with ordinary supervision methods. Problems like weak supervision targeting ability, passive, lagging and extensive supervision required the positive feedback mechanism construction of supervision interactive with informatization to stimulate stable transition of drugs supervision system reformation under new system.

Binary Informationized Supervision Full Life Cycle Management

Binary New Features of Supervision and Informatization

The domestic drug administration system was started from restructure of the State Council in 1998. Supervision inspection, inspection and testing, and risk monitoring were the “tripartite” of drug supervision system to support the internal and external work of drug supervision. After 21st century, Internet and informatization technique intervened government administration territorial. They played a solidification, upgrading and reengineering role in food and drug supervision operation process. Step by step, they became effective methods to increase operation efficiency and decrease supervision cost. As entity of supervision, inspection, testing and monitoring, merge with virtual administration informatization to form the binary structure of drug supervision. The management of supervision operation was apposed and crossover with informationized full life cycle designing. New features of supervision and infomatization binary were emerged.^[1] Performance appraisal was applied and full life cycle management purpose was verified and upgraded systematically.

At presents, drug supervision power was constantly increased and demands of precise supervision and promptness were higher and higher. More discreet and hidden violation behaviors

and methods of enterprises became new issues of the drug supervision under new system. Meanwhile, government supervision personnel faced the problems like multiple tasks, higher stress, lacking of human resource and high demands. How to solve the issue of insufficient, unbalanced resource setting between supervision capability and supervision tasks? Binary structure of supervision and informatization should be optimized. Social co-governance mode of “regulation + scientific technology” should be applied. Especially informatization methods should be wielded to realize traceable, auditable and visual food and drug safety, also, to increase supervision ability and supervision performance.

Since the institutional reformation of food & drug administration started from 2018, drug going public and drug production supervision were separated, drug distribution and usage formed market comprehensive mode with food operation. Specialization, professionalization and integration coexisted and became supervision features under new system. How to realize drug professionalization and comprehensive supervision’s mutual communication and standardized operation? Supervision and informatization binary structure framework designing needed to be applied to realize the food and drug supervision SOP designing and rebuilding.

Analyze of Drug Supervision Full Life Cycle Management

The *13th Five-Year Project of the State’s Drug Safety* clarified that “to emphasize whole process, full life cycle supervision” and administrative reform requirement” whole process marking, and traceable responsibility” under” Double random and a public” supervision mode. From laboratory research to clinical application, full life cycle management with “whole varieties and whole process” needed to be realized. Relying only on the traditional resource setting mode and supervision methods was far from adequate to realize supervision purpose ”traceable production and accountable responsibility”.

The full life cycle management of drug supervision system was the regulatory approach of registration, security, distribution, and inspection that was subsequent approach of drug researching, production, operation and usage linkages. The concept of full life cycle management was original came from the enterprises’ products full life cycle management. As the base of researching, production, operation and usage life cycle link, enterprises cared about the drug products while authority focused on drugs’ risk or the responsible subject. The focus point and content were entirely different between authorities and enterprises. For instance, novel industry drugs’ MAH (Marketing Authorization Holder) system was emerged currently. In authorities’ view, drugs full life cycle management connotation was majorly changed as before and after gone public or MAH supervision and non-MAH supervision. Supervision and informatization binary structured data decision tool needed to be applied to adapt to the reformation of organizational structure. Informatization was mainly focused on process rebuilding while the supervision was focused on resources setting. Virtual and entity mutually coordinated to adapt themselves to the reformation of both governments’ and enterprises’ organizational structure. In 2008, authority pursued the drugs’ digital supervision code. It started code assigning from the production link, through medical commerce distribution, to informatization construction applied medical facilities. The essence of it was to realize full life cycle supervision by enterprises action of code assigning. By risk information management of production full life cycle, authority could achieve the full life cycle management of drug supervision (Figure 1)

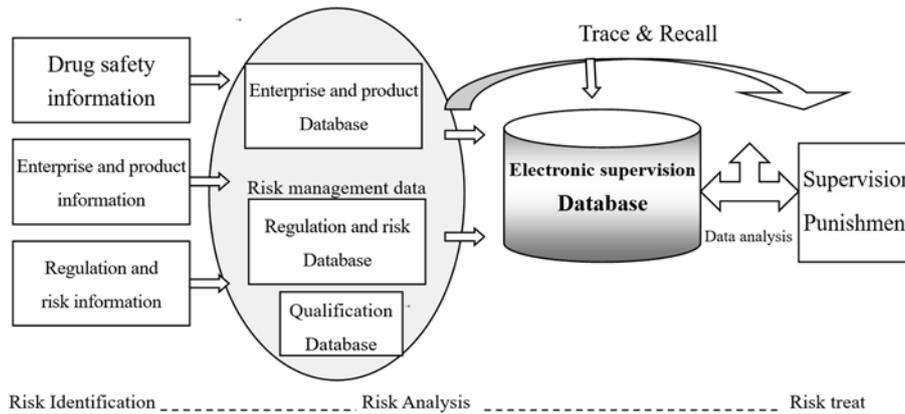


Figure 1. The risk information management of drug supervision full life cycle

Analysis of Informatization Project Full Life Cycle Management

Drug safety informatization technique project was an effective method to decrease supervision cost and enhance supervision performance. It could sufficiently save time and workload of the primary supervisors of repeatedly input inspection, monitoring and inspection information. Supervision department could be free from heavy huge-crowd strategy because of it. It was aiming to improve the work efficiency of food and drug administration work. Currently, Internet application expanding was gradually moved from “human communicate with information”, to “human talk to data”, in future, “data communicate with data” [2]. Data was separated from informatization, and gradually became an efficient technical support tool of drug supervision. Data became the fourth wheel of drug supervision vehicle with inspection, testing and monitoring. Data technical support was not simple add operation, but catalytic effect of product or exponential order. In some province or cities, food and drug administration informatization project construction might lacked of scientificity in data collection method. Problems like inaccurate data, missed data and unreal data still existed. Optimization and upgrading needed to be done by applying informatization project of full life cycle management philosophy and method.

Currently, Shanghai and some provinces and cities proposed and practiced the “One office network for all”, “Intelligent supervision” and other informatization construction projects. From establishment to acceptance checking of informatization project, the “One office network for all” reformation and construction of “Intelligent supervision” platform on drugs, cosmetics, medical apparatus and devices all relied on informatization technology applied on full life cycle management. Drug informatization project of full life cycle management should not apply informatization for informatization. The acceptance checking was just the beginning of informatization. The investing and pilot of informatization project, cooperated with establishment and realization of informatization evaluation system could update and reform existing software. Necessary condition after evaluation of informatization project could be implemented.

By the full life cycle of informatization project, supervision operation process could be settled to solve operation process shackles in informatization construction. As a result, project management standards of food and drug supervision informatization full life cycle could be formed and the full life cycle management of food, drugs, and relevant products could be promoted and ensured.

Technological and Systemic Analyze during Supervision Informatization Construction

Systemic Analysis of Supervision Informatization Construction

Currently, constructions of drug supervision informatization of various provinces and cities started around the year 2000. By nearly two decades of informatization construction cycle five informatization application systems was formed including administrative examination and approval, daily supervision, operation monitoring, comprehensive application, and website office. Although the time differences of various systems development, they all became the systemic community of

FDA informatization and played positive roles on specific supervision work in particular stages.

Base on the reality of the supervision information's binary structure with new features and independence of data resources, the drug supervision information construction was split into two fields of supervision and informatization. On the other hand, data independence from informatization techniques became developed facts. (Chart. 2) Supervision was mainly targeting to food and drug safety while the informatization was aiming to the application of informatization technologies and usage of data resources. Data became new tools supported by supervision techniques. The traditional statement "information islet" phenomenon was due to the supervision information construction issues. From the sight of developing stage "human talk to data", the shackle of SI construction was long gone. As advanced stage of informatization service development, data decision tools would be applied on evaluation of supervision performance. Meanwhile, the performance of supervision work would be effective, and it would respond on application and efficiency of informatization construction. By usage of supervision data resources, purposes like food and drug risk alarming, targeting supervision and precise supervision could be realized to inspect supervision results.

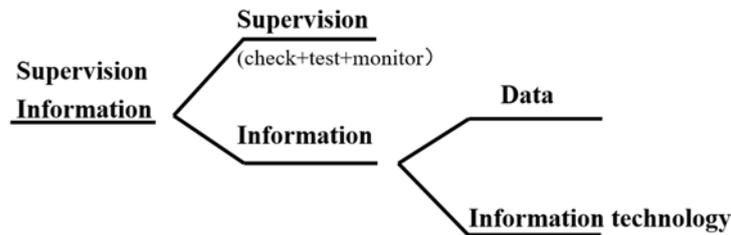


Figure 2. Road of Specialized split and independent during the supervision information

Reengineering of Supervision Informatization Operation Process

Currently, FDA operation was facing systemic reformation issues of heavy workload, human resources lacking and inadequate abilities. By relying on the current human resources setting and law enforcement equipment standards of the *Guidance standard of national FDA institutional law enforcements' basic equipment setting* (CFDA Finance [2014] No.204), it was far from adequate to respond food and drug safety risk management of resources setting demands such like *Food Safety Model City, Four Basis & Two Responsibilities*. As a result, to realize FDA operation process reengineering, informatization project construction was required, especially comprehensive integration of informatization hardware construction + data decision technique. During informatization project construction, technical standard need to be focused, usage standard was also important, especially technical standards related with supervision operation process.

With projects like big data, "Internet plus" brought by the central committee and the state council in 2015, FDA informatization construction process were accelerated and blended into FDA operation process in various provinces and cities. Shanghai food and drug safety "13th five-year" plan development framework "Digital FDA", which was the develop pathway transformation from information center to data center, had demonstrated the history of drug supervision informatization development. SHFDA informatization was developed from simple informatizational application such as original administrative examination and approval, website office, and daily supervision to deeper informatizational application such as operational monitoring and comprehensive application, even to the researching of data application service mode of drugs, cosmetics, medical apparatus and instruments big platform^[3].

Transformation of Digital Technique +Data Supervision Informatization

FDA informatization was to initially focus on the information technology construction. The situation transform in 2015 into focus on data, information, and AI application. Functions like "Human talk to machine" and "machine helping human" were partially realized. The core of informatization service was the development and integration of data. Data independence from informatization management would be inevitable. FDA informatization had showed professional

dividing trend of information technology and data decision, in another word, internal logic of supervision information center transfer to data center. In nowadays, local authorities' information center only focused on informatization construction or information technology service. Supervision operation process could not be traced. Organizational reformation was necessary to be realized.

Under new system, informatization construction needed to cover multiple operation demands including administrative approval, supervision and law enforcement, random sampling detection, risk monitoring, complaint reporting, and traceability management. By only informatization construction to fulfill these demands, it would be inadequate to cooperate with supervision purpose of inspection, testing and monitoring "tripartite". In order to satisfied objective demands of government administration operation process reformation under Internet environment and intelligence urban mode, FDA informatization construction should divide data decision from supervision informatization into an independent pathway by optimized framework designing and specialized division, in another word, the specialized division of informatization technology +data decision.

During the management period of transformation from informatization construction to information center, informatization construction was the "first chair" project. Attention and pioneer trial of management was the key to informatization project success. However, informatization demands was not base on individual needs, but result of collective discussion even the result of the wisdom of classes from bottom to top. In mode of transformation from informatization service into data decision, by cleaning, combing and compiling decisions, information data could have effect on administrative supervision system. Information technology was basic support condition, and data decision was the upgrading and application. The supervision information transformation of information technology + data was aimed to fulfill supervision work objective demands. By applying binary full life cycle management method, positive supervision information feedback mechanism could be established, and transformation upgrading of FDA informatization engineering project could be promoted.^[4]

Positive Feedback Mechanism Mode Analyze of Supervision and Informatization

Positive and Negative Effect Analyze of Binary Full Life Cycle Management

The efficiency of FDA informatization construction was relying on the regulatory effect of products' full life cycle. The effect of full life cycle of information project management benefited from the software quality improvement of the application, upgrading and transformation of the supervisory work feedback system. FDA supervision and informatization construction was reciprocal causation, in another word, supervision and informatization formed positive and negative effect, by operation process of their full life cycle, supervision performance evaluation and software quality can be improved. Effective binary structure of supervision information was benefited from the separating and compiling of data decision.

Optimizing of the supervision information binary structure gone through positive and negative effect between these two to amend and improve to give the supervision information construction a full role on maximum social effect. The effect of FDA work performance was the internal demands of local authorities' territorial supervision responsibility. In August 2016, food safety commission of the state council proposed the territorial supervision responsibility evaluation policy requirements of "adequate responsibility, jobs, human resources and methods with daily supervision and inspection responsibilities". In 2015, the event of establishing national foods safety demonstration city began. These all revealed the inevitability of governmental supervision operation process reformation and informatization technologies application. From the sight of informatization construction full life cycle management, informatization service was divided into informatization technology and data informational decision, in another word, the operation mode of information technology support and data decision service; it would give data decision the function of testing local authorities' FDA work performance. "Merit" and "fault" of supervision work were based on data evaluation.

In return, resources setting situation of drug full life cycle supervision and supervision performance had feedback effect on informatization construction result, forcing system to adapt and optimize data collection. By reformation of the supervision operation process and practical work suitability, informatization construction plan, software reformation and upgrading direction can be inspected.

Design and Practice of Supervision Informatization Positive Feedback Mode

By using data decision tools to exert the positive feedback affect of both supervision and informatization, the binary structure of supervision and informatization could realize FDA informatization’s efficient function. Usable data would be positive feedback while useless data would be negative feedback. Data decision became the key point of supervision information binary full life cycle management. Full life cycle management of supervision operation process included administrative approval, supervision law reinforcement, inspection testing, risk monitoring, and traceability management. Full life cycle of informatization construction included informatization demands, system development, software delivery, training and using, system operation and maintenance, upgrading and reconstruction and other processes. Data information was separated from full life cycle of informatization construction project into its independence. It became the bond linking supervision operation process and informatization technologies support. It also became the intermediary of applying supervision performance evaluation and validation and upgrading of system.

The supervision information positive feedback mechanism construction framework included: products full life cycle supervision, informatization project full life cycle management, and mediation of data decision. Data decision toolbox based on informatization platform could evaluate supervision performance, test and judge supervision operation process efficiency. Enhanced or improved executive plan of supervision operation process could be issued. Base on data decision analytical information, FDA work could verify information system operation efficiency and propose plan advices to upgrading or reformation. the supervision information positive feedback mechanism cycled to realize FDA informatization operation effectively. (Figure 3.)

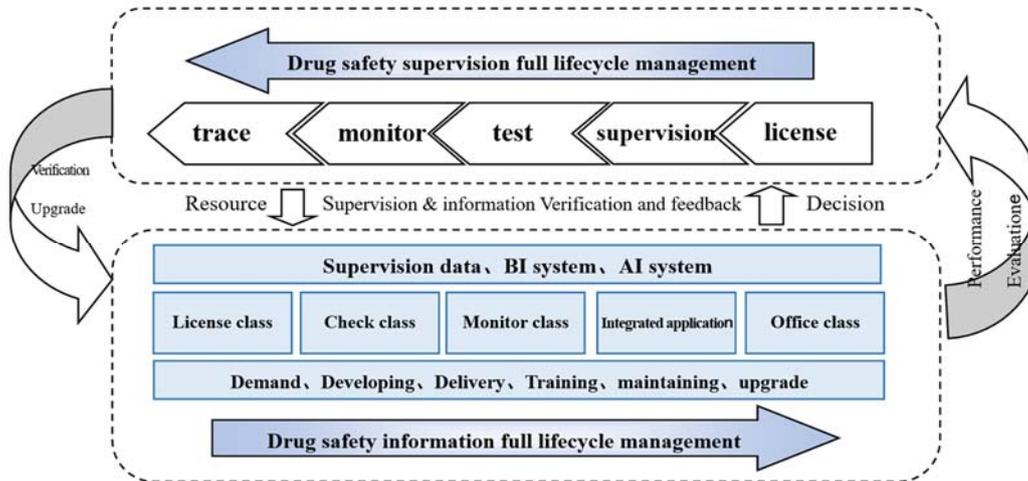


Figure 3. Positive feedback diagram between drug supervision and informatization

According to the demands of city council’s Promote “one online office for all” comprehensively to accelerate intelligence government construction, SHFDA took two methods of operation process reformation and technical reformation, in another word, optimized interaction of the supervision information binary structure, to realize “one online office for all”. In reformation of supervision operation process and performance evaluation, FDA targeted to peculiarities of FDA service to implement “triple saving” (Save linkage, save documents, save time) according to the principle of “risk classification, and scientifically saving volume”. In reformation of informatization construction technologies, FDA implemented “digital signature” real-name authenticated digital signature”, “digital license and photo” and other techniques to realize “Online process in whole

operation” of enterprise declaration, technical appraising, administrative approval, enterprises’ digital license and photo acquiring. In July 2018, SHFDA examination and approval platform completed the cloud migration of electronic government^[5]. In the same time, it also successfully docked with “One online office for all” platform of Shanghai, China. First patch of 12 issues had realized “Online process in whole operation” and “One online office for all” pilots including food operation permit, drug production permit, medical, clinical trial record of medical apparatus and instruments, and cosmetics production permit. Currently, SHFDA had separate data information from informatization construction. Transformation from information center to data center was also realized^[6]. Big platform of drugs, cosmetics, medical apparatus and instruments was successfully applied in FDA safety risk alarming and daily supervision work^[7].

Systemic Security of Supervision Informatization Positive Feedback Mode

The managing philosophy of supervision information binary full life cycle improved the establishment and perfection of drug safety supervision and informatization positive feedback mechanism. Informatization project full life cycle management solidified supervision operation process. It also solved the shackles of operation process during informatization construction. From laboratory to clinical trial, full life cycle of drug supervision must rely on informatization technical project management of full life cycle. Drug full life cycle management was premise and foundation of informatization full life cycle management.

Firstly, in early stage of informatization construction, framework was built by centralized project with big project for beams and small one for web. For instance, integrity project of Shanghai drug supervision had established basic Internet framework. By new medical health care, intelligence supervision framework with program, unified personnel, permissions, and basic data as the foundation was established.

Secondly, Internet security was the foundation of supervision informatization construction. “Without Internet security, there would be no national security”.¹ Internet security and informatization work was the basic conditions of FDA supervision information to function. In systemic security of the supervision information internet security, relationship of security and development must be carefully deal with. Drug safety issues had interwovenness connection with the public dietary and medication safety. In the supervision information binary structure, Internet security belonged to the territory of information technology service, and was at the bottom of information technology. Lack of attention and punctuality on internet security would affect on work performance of drug full life cycle supervision. Thirdly, the supervision information construction was “first chair” project. The supervision information construction was original came from supervision demands. Systemic arrangement of management levels’ attention and pioneer trial could enhance efficiency of the drug supervision information positive feedback mechanism.

Fourthly, as the intermediary for the supervision information binary structure to function, in data security, there were existences of inadequate and dislocated usage of data resource. According to the data resource usage principle of “Those who developed it should benefit from it”, data decision information created during the supervision information binary full life cycle management should mainly serve the upgrading and reformation of supervision operation process evaluation and system validation.

Develop Pathway of Supervision Informatization under New System

Establishment of Big Data Supervision Performance Evaluation Mechanism

As local primary FDA resources were limited, drug safety risk alarming and risk control became the reason to realize effective supervision philosophy transformation for governments at all levels. Currently, because of all sectors of society’s objective demand toward drug safety traceability and Internet food novel industries’ (Wechat, website, APP) commercial environment construction policies, it became necessary to apply “big data” and “Internet plus” to serve FDA work in order to improve social governance’s delicacy and efficiency.

Under the new system, drug production supervision was separated from market administration comprehensive mode and professional supervision was performed in drug production supervision. How to implement specializational professional supervision in drug distribution and usage area? Meanwhile, in FDA work performance evaluation, by only traditional modes of table reports or direct info report, high supervision cost phenomenon such as huge workload, duplicate information input and information report unpunctually existed. Base on the effectiveness and punctuality of data decision, using positive feedback mechanism under the supervision information binary structure application to construct big data supervision performance evaluation mechanism and mode could improve effective development of supervision work and informatization technical efficient service under new system.

Application of Precise Supervision Informatization Techniques

Base on exploring of “Internet plus” digital government, big data philosophy, intelligent supervision and other relevant application, precise supervision of FDA work became policy demands of drug specializational supervision performance evaluation and “delegate power, streamline administration and optimize government services” administration reformation under new system.^[8] With the aid of positive feedback mechanism and data decision tools under the supervision information binary structure, precise supervision of social co-governance could be improved to save cost and time for supervision, and also, to realize transformation from rough to precise supervision.^[9]

Supervision process, informatization technologies, data intermediary were basic elements of drug precise supervision development.^[10] According to drug digital supervision code application, drug production field inspection risk classification, regulation of food production operation risk classification, enterprise creditability classified supervised situation, traceable system construction situation and local enterprises’ operation situation, classification form of primary supervision resources setting should be compiled. Informatization technologies such as AI, BI, GPS should be applied to explore elaborating, targeting and punctuality of FDA work. Comprehensive application of supervision process relevant data was the establishment and improvement of the supervision information binary structure positive feedback mechanism.

Usage of Supervision Information Construction Collective Intelligence

Supervision information application and development was the result of collective participation. Informatization project construction’s “first chair” program was an important condition for resource inputting and application demonstration. Further development of informatization application scenario and optimization of supervision operation process were the crystallization of collective intelligence. As matter of fact, collective intelligence was as equal important as “first chair” program, and the shelf life of supervision information project was more likely relied on collective intelligence. Data decision as functional supervision information binary feedback mechanism tool, its’ data resources were original came from widely using of primary supervision group. As a result, collective discussion mode that capable to reflect supervision informatization objective demands was the key to successfully fulfill supervision information project construction.

Construction achievement of drugs, cosmetics, medical apparatus and instruments big platform during FDA informatization engineering relied on the supervision information binary structure positive feedback mechanism’s information. It upgraded and redesigned original drug safety information system to satisfy real demands of primary users. It also highlighted features like punctuality, elaborating and targeting abilities of information technology development and information data decision.

Internet Security and Data security of the Supervision Information

Internet security was the fundamental condition of informatization and important systemic guarantee of informatization supervision operation process. Internet security and informatization was dual core of the supervision information construction. In November 2016, *Internet Security Law* proposed “to focus on both Internet security and informatization development” and “Internet operators should keep collected users’ information confidential strictly.” In presents’ local drug

supervision information construction, insufficient input, tedious, stressful for users and other issues still existed. Internet security and data security were not receiving adequate attention.

In local drug supervision information construction, more resources were put into hardware building and software developing while security was not focused on. FDA specifically established operation and maintenance department to solve Internet issues immediately and to well maintain Internet security during holidays and major events. Since the establishment of information center, there was not any Internet security issues that would affect supervision work occurred. By more than a decade of Internet security keeping, data security input and efficiency analytical result, applying Internet security and supervision confidential work combined management mode led to significant achievements of the supervision information Internet security and data security work.

Summary

Under new regulatory system, food and drug administration binary full life cycle management was the transformation and updating of the supervision information project construction and performance analyze evaluation. Data decision applied in information service played a role of performance evaluation, software validation and upgrading in binary structure of supervision and informatization. Establishment and perfection of FDA informatization feedback mechanism would overall plan regulatory resources. Classification and hierarchical management and FDA big data application of enterprises, products, and regulatory departments could be effectively pursued. Sufficient method of transformation from rough supervision to precise supervision mode could be realized.

References

- [1] Cong FU, Ke-qiang LI: Government departments should have an "inclusive and prudent" attitude toward new modes and new industry [J]. *China Emergency Management*, 2017,(6):22.
- [2] Qian YU. Exploration and Construction of IT Quality Information Feedback in University Information Construction[J]. *Modern information technology*, 2018,(9): 124-126.
- [3] Jian-jin GUO, Jian-ping Guo. Research on Building National Governance Capability under the Big Data Background [J]. *China Administration*, 2015,(6):73-76.
- [4] Xiang-ming Wang. National Governance Transformation in the Big Data Era [J]. *Exploration and Contention*, 2014,(10):59-62.
- [5] Shi-hui QIAO, XIONG Chao, Zhang Kaiming. Evaluation Research on Resource Allocation Efficiency of Food and Drug Supervision System [J]. *Hubei Social Sciences*,2014,(8):19-23.
- [6] Hong WANG, XU Shizhong. Discussion on the Function and Structure of Smart City Big Data Center [J]. *Communication Technology*, 2017,(7): 94-98.
- [7] Rong XIAO. Research on the Construction of Smart Cities Supported by Big Data [J]. *China Management Informationization*, 2018,21(20):195-196.
- [8] Ying WANG, Guang-ping WANG. Research on Food & Drug Safety and Precision Supervision Based on Grassroots Classification and Classification Management [J]. *Food Safety Guide*, 2018,(4):29-30.
- [9] Fan R E, Chen P H, Lin C J. Working set selection using second order information for training support vector machines[J]. *The Journal of Machine Learning Research*, 2005, 6: 1889-1918.
- [10] Special journal feature. Focus on the Chief Data Officer, Analyze the industry pain points, and understand the data value. [J]. *Chinese and Foreign Corporate Culture*, 2018,(8):23-25.