

Digital Financial Inclusion and Formal Entrepreneurship: The Roles of Business Entry Institutions and Regulatory Quality

1. Muhammad Aizaz Khan, 2. Abdul Razzaq, 3. Kiran Afzal

1. BS Student, Quaid I Azam School of Management Sciences (QASMS), Quaid I Azam University
Islamabad, Pakistan

2. Assistant Professor, Quaid I Azam School of Management Sciences (QASMS), Quaid I Azam
University Islamabad, Pakistan

arazzaq@qau.edu.pk (Corresponding author)

3. PMAD, Ministry of Defence, Pakistan

Abstract

Digital financial inclusion has emerged as a key policy instrument for promoting entrepreneurship and inclusive economic development. However, existing research provides limited insight into the institutional mechanisms through which financial inclusion translates into formal business creation. Drawing on Institutional Theory, this study examines the relationships among digital financial inclusion, domestic private-sector bank credit, the business-entry environment, regulatory quality, and formal entrepreneurship. Specifically, the study investigates the mediating role of the business-entry environment and the moderating effect of regulatory quality. Using cross-country secondary data obtained from the World Bank's Global Findex Database, Business Ready (B-READY), Enterprise Surveys, World Development Indicators, Entrepreneurship Database, and Worldwide Governance Indicators, the proposed framework is estimated using regression-based mediation and moderation analyses.

The findings indicate that digital financial inclusion and domestic private-sector bank credit positively influence the business-entry environment, which, in turn, significantly promotes formal new-business creation. The business-entry environment also mediates the relationship between domestic private-

sector bank credit and new business density, while regulatory quality strengthens the positive association between the business-entry environment and formal entrepreneurship. However, female participation in firm ownership does not exhibit a statistically significant independent effect on the business-entry environment.

This study contributes to Institutional Theory by demonstrating that financial resources promote entrepreneurship not only through greater financial access but also through institutional mechanisms that facilitate business entry. The findings further suggest that governments should complement financial inclusion initiatives with reforms aimed at improving business-entry procedures and strengthening regulatory quality to achieve sustainable entrepreneurial development.

Keywords: Digital financial inclusion, Formal entrepreneurship, Business-entry environment, Regulatory quality, Institutional theory

1. Introduction

Small and medium-sized enterprises (SMEs) play a vital role in modern economies owing to their importance in creating employment, innovations, competitions, regional developments, and diversification. The importance of SMEs is more apparent in emerging and developing economies as they serve the income generating function and allow the growth of the formal private sector and participation in both domestic and foreign markets. Around the world, more than 90 percent of companies and more than 50 percent of total employment belong to small and medium-sized enterprises, but their development is hindered by lack of access to capital, constraints in managerial capability, information asymmetry, and institutional weaknesses (Ahmed, 2025). Among the constraints faced by small and medium-sized enterprises, lack of access to formal capital becomes particularly relevant.

Traditional financial institutions tend to consider SMEs and young businesses as risky borrowers because there may not be any information available on the financial status of borrowers, ability to pay back money, and future cash flow. As a result, the asymmetry of information creates the costs of screening and monitoring that makes banks place higher collateral conditions, higher interest rates, or even credit rationing. This constrains access to capital reduces the ability of the firm to acquire technologies, hire competent workers, develop products, enter the market, and cope with unexpected economic fluctuations. Governments try to resolve these problems using credit guarantee systems, subsidized loans, government investment, and business development initiatives.

The growth of digital finance has introduced a potentially transformative response to these longstanding financing barriers. Digital financial inclusion extends the reach of formal finance through mobile-money services, digitally enabled bank accounts, online lending, digital payments, crowdfunding, and other technology-supported financial services. By lowering transaction costs, simplifying payment and account-management processes, and improving the availability of alternative information, digital finance may allow financially underserved businesses and entrepreneurs to participate more effectively in the formal financial system. Account ownership at a financial institution or through a mobile-money-service provider, the measure adopted in the present study captures an important access dimension of digital financial inclusion.

Recent empirical evidence generally supports the economic potential of digital financial inclusion, but it also demonstrates that its benefits are not automatic. Zhang, Jin, and Li (2025), using panel data from Chinese listed SMEs, report that digital financial inclusion contributes to the high-quality development of smaller firms. Zhang, Dong, Wang, and Li (2025) similarly find that the breadth of digital inclusive finance coverage is an important mechanism through which financial digitalization supports SME development, although the effects of usage depth and the degree of digitalization are not fully realized and differ across industries and regions.

Further evidence from 2026 strengthens the contingency approach. In this regard, Pereira et al. (2026) report that FinTech adoption increases innovation within listed French SMEs and the financial performance of listed SMEs in the United Kingdom through facilitating credit access, payments, and lowering transaction costs. Significantly, their results also indicate that other aspects like governance knowledge and financial literacy affect the extent to which these benefits can be achieved. Likewise, Siddiqui and Rokade (2026) report that access to finance is one of the aspects complementing entrepreneurial orientation and entrepreneurial skills to promote innovation and the performance of MSMEs. Together, these studies imply that while financial resources afford performance opportunities, entrepreneurial and organizational processes determine if such opportunities are successfully realized.

Nonetheless, the most recent studies continue to focus mainly on empirical findings at the level of individual companies operating in one country or a small number of highly developed countries. Zhang, Jin, and Li (2025) and Zhang, Dong, Wang, and Li (2025), for example, study listed SMEs in one financial and institutional system, China. Pereira et al. (2026) consider listed firms in the UK and France, which feature a highly developed system of financial markets, technological infrastructure,

disclosure, and regulation. On the other hand, Siddiqui and Rokade (2026) rely on survey evidence regarding MSMEs in India. These studies offer interesting findings, but they cannot be generalized to countries featuring significantly different financial, institutional, technological, and entry environments. According to institutional theory, organizations exist in institutional systems of norms, formal and informal rules that affect the access to resources, transaction predictability, and the very legitimacy of economic activity (North, 1990; Scott, 2014). Regulatory quality, legal systems, financial supervision, protection of property rights, and administrative effectiveness are examples of formal institutions that lower uncertainties and establish the environment in which the investment can be made by entrepreneurs and firms. Weak institutions lead to higher transaction costs, lower contractual certainty, more possibilities of arbitrary action, and lower productive use of externalities. Institutional environment should thus not be seen as just another explanatory variable; it is the environment that determines how financial inclusion, credit creation, and entrepreneurship translate into business creation.

The dependency of digital finance on the institutional environment has become increasingly evident in recent academic literature. Ahmed (2025) proves that crowdfunding enables access to entrepreneurial finance and SME finance; however, the growth of crowdfunding requires an enabling regulatory environment that both promotes innovation and financial stability and also protects the interests of the investors and consumers. On one hand, over-regulation may hinder innovation and create excessive compliance costs, on the other hand, it may leave entrepreneurs and investors unprotected from fraud and instability. Therefore, the usefulness of digital finance depends on regulatory design and not on institutional neutrality. More direct evidence between cross countries is presented by Hassouba et al. (2026), who look at FinTech adoption, institutional quality, and financial development in emerging and developing economies. They find that FinTech adoption is related to financial development positively, and this relation gets stronger as institutional quality rises above a certain threshold. Yet, the dependent variable in this case is financial development and not formal business creation. Thus, even recent cross-country evidence leaves the digital finance-entrepreneurship link incompletely explained.

Domestic credit should also be rethought. Increased credit by the banking system to the private sector can reduce liquidity constraint and stimulate investments and new businesses. Nevertheless, the overall increase in credit can be misleading since it does not necessarily mean targeted government support and equal distribution among SMEs. Credit could be provided by big, already established, and politically connected firms, while smaller and new firms are still rationed. The efficiency of the

domestic credit could be reduced because of weak financial intermediation, borrower screening, high costs of interest, inefficiency in the allocation of resources, and institutional capture. In this respect, the current paper views this construction as domestic private-sector bank credit, thus bringing theory and measurement together.

Another aspect relates to the business entry environment. Entrepreneurship may be studied from the individual firm's perspective by means of such indicators as entrepreneurial orientation, innovativeness, proactiveness, opportunity identification, risk taking, leadership, and entrepreneurship skills. Recent empirical research proves that such skills may contribute to the transformation of financial and ecosystem resources into innovation and performance (Siddiqui & Rokade, 2026). In the current study, the corresponding variable is the B-READY Business Entry Overall Score provided by the World Bank. It represents the quality of regulations, public services, transparency, and efficiency associated with the creation of a formal business, rather than the personal entrepreneur's skills or orientation.

Therefore, in order to ensure consistent approach to the problem, this construct is viewed as a business entry environment. This environment may reduce bureaucratic procedures, expenses, uncertainties, and difficulties related to the registration of a business, and thus facilitate transforming financial access and opportunities into registered firms. On the other hand, inefficient business registration procedures, fragmented digital services, uncertain requirements, and lack of administrative transparency can discourage formal business formation despite the availability of financial services. Thus, the business entry environment can be considered as the institutional channel through which the financial environment can affect new business density. The dependent variable must be carefully interpreted as well. New business density refers to the number of limited-liability businesses formed per 1,000 individuals aged 15-64 years in a calendar year. This means that new business density can be regarded as an indicator of formal business formation and not the profitability, efficiency, survival rate, growth of sales or performance of existing small businesses. In order to prevent construct inflation, the present study will use new business density or formal new business formation as the dependent variable. This adjustment greatly improves the validity of the current research as it ensures consistency between theory and practice.

Institutional gender inclusion constitutes another crucial yet institutionally anchored aspect of entrepreneurship development. The increased participation of women in firm ownership could enhance the supply of entrepreneurs, promote household and community welfare, and ensure greater

inclusiveness in economic participation. Yet, women-owned and women-participating businesses usually suffer from discrimination in access to capital, assets, professional networks, management assistance, and markets. The definition of female participation in ownership should be understood within the context of the institution rather than considered as a biological deficiency in the capacity for entrepreneurship. The contemporary empirical evidence corroborates this institutional perspective on entrepreneurship and gender. Rafiq et al. (2026) establish that women's entrepreneurship and institutional quality are conversion factors through which the digital economy affects social sustainability in European economies. According to their study, the participation of women in entrepreneurship delivers greater developmental outcomes if institutions allow the entrepreneurial agency to generate economic and social impacts. Nonetheless, their dependent variable is social sustainability, and their study does not indicate whether the female participation in firm ownership stimulates formal firm creation in a different institutional environment around the world.

The measure of gender used in the present study is based on the proportion of firms that have participation by women in their ownership. The variable cannot be said to show the presence of majority ownership, managerial control, being the primary entrepreneur, or having a small share of ownership by women. The term used to refer to the concept should therefore be "female participation in firm ownership" rather than "entrepreneur's gender." The positive relationship should be seen as suggesting that ownership inclusiveness is associated with greater entrepreneurial development while the negative one should not be considered as showing less capability of women. Instead, the relationship could show discrimination in the structure, restriction of financing, sectoral concentration, informal business, lack of decision-making power, or institutional factors that stop women from realizing full benefits of ownership.

Recent literature has provided more complex evidence on how digital finance can help SME innovation and development, entrepreneurial competencies can facilitate financial resource management into firm performance, regulation design can affect alternative finance, and institutional factors can enhance FinTech's role in financial development (Ahmed, 2025; Hassouba et al., 2026; Pereira et al., 2026; Siddiqui & Rokade, 2026; Zhang, Dong, et al., 2025; Zhang, Jin, & Li, 2025). However, this literature continues to be fragmented by construct, country, outcome, and level of analysis. It does not provide a cohesive understanding of how national-level financial inclusion, credit in the banking sector, gender-friendly ownership, institutions of business entry, and regulation quality affect formal business entry collectively.

The first theoretical lacuna exists due to the fact that while literature on digital finance usually concentrates on financing availability and cost reductions, the institutional literature highlights regulations or governance. These two strands of literature fail to explain the connection between financial availability and formal institutions in determining firm formation. The open theoretical question is thus not only about the effect of digital financial inclusion on entrepreneurship, but also about how financing availability is turned into business formation. Secondly, there is a methodology gap since recent studies tend to focus on cross-sectional surveys, single country samples, or short firm-level panels. While this is useful for perception and organizational capability assessment, the control of country heterogeneity, time adjustment, reverse causality, and endogeneity is limited. In the current study, these methodological issues are being addressed using an international harmonization design and hypothesis-driven analysis that directly, indirectly, and conditionally test the hypotheses in question. Thirdly, there is a policy gap, in that financial inclusion, private sector credit development, women's entrepreneurship, and regulatory reform have been pursued as independent policies. However, new empirical research shows that they are interdependent. Digital financial accounts will not promote entrepreneurial ventures where registration costs and regulatory uncertainty are high; credit development may pass over young and small firms; women's entrepreneurship participation may fail to create inclusive growth if women do not control the resources; and regulatory reforms may be meaningless when financial access is still restricted.

2. Literature Review and Theoretical Framework

2.1. Conceptual clarification and alignment of the hypotheses

Before developing the hypotheses, the theoretical constructs must be aligned with the indicators used in the empirical model. The original formulation refers to the dependent variable as SME performance, although it is measured through new business density; labels the percentage of firms with female participation in ownership as entrepreneur's gender; represents government support through domestic credit to the private sector by banks; and measures entrepreneurship through the B-READY Business Entry Overall Score. The hypotheses therefore require reformulation so that the theoretical claims do not exceed what the indicators can validly capture. Accordingly, this section uses digital financial inclusion for account ownership at a financial institution or through a mobile-money provider; female participation in firm ownership for firms with female ownership participation; domestic private-sector bank credit for credit provided by banks to the private sector; business-entry environment for the B-READY Business Entry Overall Score; regulatory quality for

the World Governance Indicators regulatory quality measure; and new business density for new limited-liability registrations per 1,000 working-age people. This terminology preserves the substantive intention of the original hypotheses while establishing consistency between theory and measurement.

2.2. Institutional theory as the overarching theoretical foundation

The institutional approach offers the primary theoretical foundation for the analysis of variation in entrepreneurial creation across countries. According to this theory, entrepreneurial behavior is embedded within the set of formal rules, processes, systems of enforcement and socially accepted practices that determine what economic behaviors are feasible, acceptable and predictable. Institutions can lower or increase the level of uncertainty by determining the costs of transactions, access to resources, enforceability of agreements, and reputation of public and private entities. Thus, the availability of funds cannot be a sufficient explanation of entrepreneurial behavior since the effect of financial assets depends on the possibility of using these assets in the context of institutional arrangements to create formal enterprises.

North (1990) defines institutions as constraints imposed by humans that govern the nature of economic, political, and social interactions. Examples of formal institutions are legal and regulatory frameworks, property rights systems, while informal institutions consist of norms, conventions, and codes of conduct. This notion is expanded by Scott (2014), who specifies three types of institutional dimensions such as regulative, normative, and cultural-cognitive. The first of them is especially significant for the model proposed here as business registration, financial market regulation, and regulatory quality have an effect on costs and predictability of the entrepreneurial entry process.

Recently conducted empirical study proves both the significance and insufficiency of the institutional approach in entrepreneurship studies. According to Urbano et al. (2026), institutional dimensions play different roles regarding various aspects and stages of entrepreneurship, and their interactions are still understudied. It supports the idea that regulatory quality should be seen not just as one more independent variable but as a context which changes effectiveness of financial and entry institutions. Institutional theory is particularly useful in the current research because it helps to understand why the same degree of financial access could lead to different degrees of formal entrepreneurship creation, why widespread private finance could fail to spur new entrepreneurship if the loaning system is ineffective or biased in favor of the already existing businesses, and why female business ownership

might bring about different results depending on different institutions. Thus, the theory suggests that financial means work via an environment of business creation.

2.3. Digital financial inclusion and the business-entry environment

Digital financial inclusion expands the potential reach of formal financial services by reducing geographical, administrative and transactional barriers. Mobile-money accounts, digitally enabled bank accounts and related financial technologies may lower the time and cost of receiving payments, transferring funds, maintaining liquidity and establishing financial records. These services are particularly relevant for prospective entrepreneurs who lack access to conventional branch-based banking or do not possess the collateral and documentation usually required for traditional borrowing. Theoretically, digital financial inclusion can improve the business-entry environment through several mechanisms. Account ownership facilitates the separation of household and business finances, digital financial records can reduce informational opacity, digital payment systems can lower entry costs, and financial access may complement electronic business-registration and tax-payment systems. Wei et al. (2025) finds that digital financial inclusion increases entrepreneurial activity and that e-commerce development transmits part of this effect. Xiang et al. (2025) show that digital inclusive finance strengthens SME innovation by alleviating financing constraints. Li and Pan (2025) similarly report that digital inclusive finance improves rural entrepreneurial survival, particularly among entrepreneurs with stronger digital and financial literacy.

The newest evidence further suggests that digital finance should be understood as an ecosystem resource rather than an isolated technological input. Pereira et al. (2026) find that digital-finance integration supports innovation and financial outcomes among SMEs, but that complementary governance expertise and financial literacy influence the magnitude of these benefits. The common conclusion is that digital financial access creates entrepreneurial possibilities, but complementary institutions and capabilities determine whether those possibilities can be converted into actual business activity.

H1. Digital financial inclusion has a positive effect on the business entry environment.

2.4. The business-entry environment and new business density

The business-entry environment refers to the formal regulatory and administrative conditions under which a business is established. It includes the clarity of entry rules, transparency of regulatory information, efficiency of registration procedures, availability of public services and operational

burden imposed on prospective entrepreneurs. Unlike entrepreneurial orientation, which captures individual or firm-level proactiveness, innovativeness and risk-taking, the business-entry environment is a country-level institutional attribute. A supportive business-entry environment can increase formal new-business activity by reducing both direct and indirect entry costs. Direct costs include fees, documentation requirements and procedural expenses. Indirect costs include delays, uncertainty, repeated interactions with public agencies and the opportunity costs associated with complex registration processes. Where entry requirements are transparent, digitalized and consistently enforced, prospective entrepreneurs can calculate expected costs more accurately and are less likely to remain informal. Conversely, burdensome procedures and unpredictable administrative decisions can discourage registration even where individuals possess viable business ideas and access to finance.

Recent cross-country evidence supports the importance of institutional and infrastructural conditions for new-business creation. Munir (2025) finds that institutional quality, digital infrastructure and economic factors jointly influence new-business formation in Muslim-majority economies. Rashid et al. (2025) similarly highlights the relevance of finance, infrastructure and regulatory conditions for entrepreneurial activity, particularly in emerging-economy settings where institutional constraints are substantial.

H2. A more supportive business-entry environment has a positive effect on new business density.

2.5. Female participation in firm ownership and the business-entry environment

Female participation in firm ownership reflects the extent to which women are represented within formal business ownership structures. It does not necessarily indicate majority ownership, direct managerial authority or the gender of a sole entrepreneur. Nevertheless, it provides a country-level signal of women's access to formal entrepreneurial opportunities and ownership rights. Institutional theory suggests that female ownership participation reflects the interaction of legal rights, access to finance, social norms, labour-market structures, family responsibilities and institutional support. Where women can own assets, open accounts, access markets and participate in business networks, a wider segment of the population can enter formal entrepreneurship. Greater female participation may also generate demonstration effects, normalize women's business ownership and expand entrepreneurial networks for other women.

Yet the association is unlikely to be uniform. Women-owned or women-participated firms may be concentrated in smaller, less capital-intensive or lower-growth sectors because of structural

constraints rather than preference alone. Zeng et al. (2026) show that country-level institutional quality can materially alter gender-related firm outcomes, reinforcing the view that representation must be interpreted within the surrounding institutional context.

H3. Female participation in firm ownership has a positive effect on the business-entry environment.

2.6. Domestic private-sector bank credit and the business-entry environment

Access to credit is central to business entry because prospective entrepreneurs must finance registration, equipment, working capital, premises, labour and initial market development before generating stable revenues. Domestic credit provided by banks to the private sector measures the scale of formal bank intermediation relative to the economy. A higher value generally indicates that the banking system allocates a larger volume of resources to private actors. However, domestic private-sector credit is not equivalent to government support. It may include lending to large corporations, households and established firms, and therefore does not establish that start-ups or SMEs receive a proportional share. The theoretical argument must consequently focus on financial-system depth and credit availability rather than targeted public assistance.

From a financial-constraint perspective, wider credit availability should support entrepreneurship by increasing the likelihood that viable projects obtain external capital. From an institutional perspective, deep private credit markets may also reflect developed information systems, enforceable contracts and established lending relationships. Li and Sun (2025) find that inclusive lending support improves SME performance, especially among firms constrained by weak credit histories, low operating efficiency or insufficient collateral.

H4. Domestic private-sector bank credit has a positive effect on the business-entry environment.

2.7. The mediating role of the business-entry environment

From the above discussion, it follows that financial assets do not necessarily have a direct impact on entrepreneurship creation. The impact of such assets depends on whether the entry system makes it possible for potential entrepreneurs to turn resource availability into business registration. The entry system could thus be seen as a mediator between domestic credit availability and business creation. This mediation is premised on the fact that there exist two interconnected links. Credit availability could increase entrepreneurial opportunities by allowing individuals to access finances for start-ups, operating capital, and compliance costs. Entry system would allow conversion of such financial opportunities into business registration through reduced procedural barriers and increased incentives

for registration. In cases where entry systems are costly and complex, extra credit could be used to finance existing businesses and other activities.

Studies in recent times tend to move away from simple finance to performance relationships and adopt an indirect approach. Wei et al. (2025) suggest the development of e-commerce to act as a partial mediator between digital financial inclusion and entrepreneurship, and Xiang et al. (2025) underline the importance of financing problems as the means of using digital inclusive finance in stimulating SME innovation. In terms of countries, the business entry environment acts as the institutional channel connecting finance and entrepreneurship.

H5. The business-entry environment mediates the positive relationship between domestic private-sector bank credit and new business density.

2.8. Regulatory quality as a moderator

Regulatory quality refers to the ability of the institutions in power to develop and implement policies and regulations that promote the growth of the private sector. Regulated quality is supposed to be different from the entry business environment in theory. Entry business environment concentrates on how the process of setting up the business occurs, while regulated quality concerns the integrity of the policy environment. Even if the entry process is streamlined, it would have more impact on a stable, cohesive and credible policy environment. A country can simplify the process of registering a business and maintain unpredictable licensing, inconsistent implementation of the policies, or unstable policies after business registration. In such a setting, prospective entrepreneurs may remain reluctant to register because the wider operating environment does not protect the expected returns from formalization.

Ahmed (2025) demonstrates that the contribution of crowdfunding to SME finance depends on regulatory design that balances innovation with financial stability and investor protection. Hassouba et al. (2026) likewise reports that institutional quality strengthens the contribution of FinTech to financial development across emerging and developing economies. These findings support a contingent institutional view in which broad regulatory quality amplifies the effect of domain-specific entry institutions.

H6. Regulatory quality positively moderates the relationship between the business-entry environment and new business density, such that the positive relationship is stronger when regulatory quality is higher.

2.9. Integrated theoretical framework

The proposed framework explains formal new-business activity as the outcome of an institutionally conditioned resource-conversion process. Digital financial inclusion, female participation in ownership and domestic private-sector credit represent economy-level conditions that broaden access to financial and entrepreneurial resources. The business-entry environment reflects the institutional channel that decides whether or not the above resources can be used to form ventures formally. Regulatory quality is the institutional context that influences the credibility, reliability, and effectiveness of this conversion process. In other words, the above framework goes beyond direct-effect hypotheses in that resources provide entrepreneurial opportunities, entry institutions convert them into formalization, and the general regulatory quality affects the conversion process.

3. Methodology

3.1. Research design and unit of analysis

This paper uses a quantitative and explanatory research approach to investigate the influence of digital financial inclusion, women's ownership in firms, domestic credit to the private sector by banks, and the business entry environment on new businesses across the world. It also investigates the mediating role of the business-entry environment in the relationship between domestic private-sector bank credit and new business density, together with the moderating role of regulatory quality in the relationship between the business-entry environment and new-business formation. The country constitutes the unit of analysis because all principal variables are measured at the national level. Digital financial inclusion represents the proportion of adults with access to formal financial accounts, female participation in firm ownership represents the proportion of surveyed firms with at least one female owner, domestic private-sector bank credit reflects economy-wide bank lending to private actors, and regulatory quality captures the institutional environment governing private-sector activity. Similarly, the business-entry environment and new business density represent national regulatory and entrepreneurial-system outcomes rather than the characteristics or performance of an individual firm.

The original research design reported an annual panel covering 2000-2024. However, the selected indicators are not all available annually over this period. Global Findex account ownership information is only available for particular survey years, whereas B-READY is a new business environment database. Consequently, creating an annual panel from 2000 to 2024 would necessitate interpolation, repetition, or backward extrapolation of the values, thus resulting in the creation of spurious variation over time. Thus, the updated research makes use of a harmonized cross-country

approach that uses the most recent comparable observations focused on 2024 to 2025. The cross-sectional nature of the harmonized data set suggests that the empirical results be considered as theoretically motivated relations, but not causations. While the study examines mediation and moderation effects, any causation statements are excluded due to the choice of data lacking temporal order between the variables.

3.2. Population and sample selection

The sample of the study includes economies that are part of the World Bank Business Ready, Global Findex, Enterprise Surveys, World Development Indicators, Entrepreneurship Database, and Worldwide Governance Indicators. The preliminary selection of samples is based on the presence of the B-READY Business Entry Score since the business entry environment is the mediator of the theoretical model developed in the study. Economies make it to the final selection in case there are comparable data regarding the variables such as new business density, digital financial inclusion, women in firm ownership, domestic private sector bank credits, business entry environment, regulatory quality, and control variables. The economies with missing values for the core variables are not part of the analysis.

The databases will be linked based on ISO three-letter codes representing countries. The country names will be homogenized prior to linking and linking of databases will be done sequentially in order to capture the observations that get lost during the linking process. The paper includes the original number of economies contained in each database, those that were left out due to absence or non-comparability of data, and the final estimation sample. As the World Bank Enterprise Surveys are not conducted for every country in the same year, the female ownership variable is chosen based on the observation that is closest to the year in question. Ideally, the window period is five years surrounding 2024. The exact Enterprise Survey year is kept for each economy to see how it affects the findings.

3.3. Data sources

The empirical analysis relies exclusively on secondary data obtained from internationally recognized World Bank databases. The use of standardized international datasets improves cross-country comparability, supports replication, and eliminates respondent-level common-method bias. New business density and domestic private-sector bank credit are obtained from the World Development Indicators. New business density originates from the World Bank Entrepreneurship Database and represents the number of newly registered limited-liability firms per 1,000 people aged 15-64.

Domestic private-sector bank credit measures financial resources provided by deposit-taking institutions to the private sector as a percentage of gross domestic product.

Digital financial inclusion is measured using the Global Findex Database. The selected indicator represents the percentage of individuals aged 15 or older who own an account at a financial institution or personally use a mobile-money service. The most recent comparable observation is used. This measure captures access to formal financial services but does not directly measure the frequency of digital transactions, business-specific borrowing, fintech investment, online lending, or the quality of financial services. Female participation in firm ownership is obtained from the World Bank Enterprise Surveys. It measures the percentage of surveyed formal firms with at least one female owner. The indicator captures women's participation in formal ownership structures but does not distinguish between majority and minority ownership, managerial control, or the gender of the principal entrepreneur.

The business entry environment is evaluated using the World Bank B-READY Business Entry Overall Score. This index measures the effectiveness of regulation, accessibility and transparency of services provided by the state, and efficiency of operations when establishing a business formally. The higher the value of this score, the more conducive and efficient the conditions are for registering and entering into business in an economy. Regulatory quality is captured through the Worldwide Governance Indicators. These indicators measure perceptions regarding the quality of the government's capacity to formulate and implement regulations and policies for private sector development. A consistent regulatory-quality scale is used throughout the analysis.

3.4. Control variables

The empirical models consider a relatively limited number of control variables at the country level that may affect both the explanatory variables and new businesses. The variable "GDP per capita" is introduced in order to capture the level of economic development since richer economies have better financial systems and institutions as well as higher market demand. "Annual GDP growth" is used as a control for economic environment and change in entrepreneurship opportunities. "Internet use" is taken into consideration as it helps in accessing financial resources, registering firms online, obtaining information, and participating in electronic markets. "Urbanization" is used as a control for market concentration, availability of infrastructure, and closeness to administration and financial services. "Education/human capital" is considered if there is data available internationally since identification

of opportunities, access to finance, and registration can depend on the knowledge of working-age population.

Regional and income-group dummy variables are added to account for broad geographical and structural differences that may not be fully represented by continuous economic indicators. However, the number of control variables is kept limited because the effective sample size is constrained by the intersection of the selected databases. Controls are selected based on theory rather than statistical significance alone.

3.5. Empirical model specification

The theoretical framework contains four direct relationships, one mediation relationship, and one moderation relationship. These relationships are tested through a series of regression equations. The first equation examines the determinants of the business-entry environment and tests H1, H3, and H4:

$$BEE_i = \alpha_0 + \alpha_1 DFI_i + \alpha_2 FFO_i + \alpha_3 DPC_i + \sum \alpha_k Control_{ki} + \varepsilon_i \dots \dots \dots (i)$$

Positive coefficients for digital financial inclusion, female ownership participation, and domestic credit provide support for H1, H3, and H4, respectively.

The second equation tests the direct effect of the business-entry environment on new business density:

$$LNBD_i = \beta_0 + \beta_1 BEE_i + \beta_2 DFI_i + \beta_3 FFO_i + \beta_4 DPC_i + \sum \beta_k Control_{ki} + u_i \dots (ii)$$

A positive and statistically significant value of β_1 supports H2 by demonstrating that a more supportive business-entry environment is associated with higher formal new-business activity after accounting for financial, ownership, and country-level conditions.

3.6. Mediation analysis

H5 proposes that the business-entry environment mediates the relationship between domestic private-sector bank credit and new business density. The indirect effect is calculated as the product of the estimated domestic-credit-to-business-entry coefficient and the business-entry-to-new-business-density coefficient:

$$IE_{DPC} = \alpha_3 \beta_1.$$

The total effect of domestic private-sector bank credit is separated into direct and indirect components. The statistical significance of the indirect effect is evaluated using non-parametric bootstrap confidence intervals based on at least 5,000 resamples. Mediation is supported when the

bias-corrected 95% confidence interval for the indirect effect does not contain zero. Because the data are cross-sectional, the estimated indirect relationship is interpreted as an association consistent with the proposed mediating mechanism rather than conclusive evidence of a causal temporal process.

3.7. Moderation analysis

H6 proposes that regulatory quality moderates the relationship between the business-entry environment and new business density. The moderation model is specified as

$$\text{LNBD}_i = \gamma_0 + \gamma_1 \text{BEE}_i + \gamma_2 \text{RQ}_i + \gamma_3 (\text{BEE}_i \times \text{RQ}_i) + \sum \gamma_k \text{Control}_{ki} + v_i.$$

Before constructing the interaction term, the business-entry environment and regulatory-quality variables are mean-centered. A positive and statistically significant interaction coefficient supports H6. The conditional effect of the business-entry environment is estimated at low, average, and high levels of regulatory quality, typically one standard deviation below the mean, and one standard deviation above the mean. An interaction plot is presented to show predicted new business density across levels of the business-entry environment under weak, average, and strong regulatory quality.

3.8. Data analysis procedure

Empirical analysis will first involve data screening and harmonization where the country identifier variable will be harmonized, duplicates will be eliminated, the measurement scale will be verified, and the year of reference for each observation will be established. Missing values for the key explanatory variables are not imputed by any means of linear interpolation, backward extrapolation, or averaging across countries. Complete-case methods are used for estimating the model unless there is a large number of missing observations. All variables are described using descriptive statistics in terms of mean, standard deviation, median, minimum, maximum, skewness, kurtosis, and interquartile range. The histograms and boxplots are analyzed in order to detect non-normality and influential observations. Correlation coefficients serve as a starting point for understanding the nature of bivariate associations; however, it cannot be assumed that they indicate causality or confirm any hypotheses. The multicollinearity problem is diagnosed by examining the variance inflation factors and the tolerance measures. The problem of heteroskedasticity is identified with the help of residual analysis and by performing tests like Breusch-Pagan test or White test. Since it is a common feature of cross-country data to have heteroskedastic error terms, the OLS regressions are performed using heteroskedasticity-robust HC3 standard errors. Model specification is checked using residual versus fitted plots and Ramsey's RESET test. Influential observations are analyzed with the help of standardized residuals, leverage measure, Cook's distance, and DFBETAs. The economies are not

omitted just because they are outliers. Where influential cases are present, results are reported both with and without those observations.

3.9. Robustness analyses

Some additional analyses are carried out to test the robustness of the results. The regression models are run on logarithm and non-logarithm variables of business density. The interaction effect between regulatory quality and the dependent variable is estimated using alternative WGI scales where every model has to use only one scale. Participation of women in the ownership of firms is measured using alternative windows of survey years to check whether time gap matters in obtaining the results. The models are also rerun after removing influential economies and, when feasible, for separate samples of developing and developed economies. Different sets of control variables are included gradually to test the robustness of key relationships.

3.10. Endogeneity and limitations of causal interpretation

The empirical associations can suffer from reverse causation, omitted variable bias, and measurement errors. Countries that have more new businesses per capita may experience greater financial inclusion or institutional changes. There can also be unobservable factors, like political stability, taxation, corruption, informality, legal tradition, or entrepreneurial culture, that may impact both institutions and business entry. The issues above can be dealt with the use of theory-driven control variables, robust standard errors, alternative specifications, influence analysis, sub-sample tests, and conservative interpretations. However, the cross-section research design does not allow completely dealing with the endogeneity problem. The findings are therefore presented as associations backing or not backing the hypothesized theoretical associations and not as causal effects. The instrumental-variable approach is not used unless there is an appropriate instrumental variable.

3.11. Research transparency and ethical considerations

The research makes use of country-level data which is publicly available in aggregate form and no respondents are contacted directly in this process. As a result, no personal data is involved in the analysis. However, all data analysis principles including data transparency are being adhered to. All databases, indicators, years, exclusions, transformations, and procedures of analysis are specified. The statistically insignificant and contradicting results are also reported together with the significant results. Hypothesis testing is separated from exploration. In order to ensure replicability, the following items have to be made public in the final version of the study: data dictionary, source information,

dates of downloads, country code crosswalk, data cleaning procedure, merged dataset for analysis (if licensing allows), estimation code, bootstrapping, robustness tests.

3.12. Measurement summary

Table 1:

Construct	Code	Role	Operational measure
New business density	NBD	Dependent	Newly registered limited-liability firms per 1,000 people aged 15-64
Digital financial inclusion	DFI	Independent	Adults aged 15+ with an account at a financial institution or personally using a mobile-money service (%)
Female participation in firm ownership	FFO	Independent	Firms with at least one female owner (%)
Domestic private-sector bank credit	DPC	Independent	Domestic credit to the private sector by banks (% of GDP)
Business-entry environment	BEE	Mediator	B-READY Business Entry Overall Score
Regulatory quality	RQ	Moderator	Worldwide Governance Indicators regulatory-quality score
GDP per capita, growth, internet use, urbanization, education, region/income group	Controls	Controls	Country-level macroeconomic and structural controls

4. Results & Discussion

4.1. Sample selection

The sample-selection procedure begins with 101 economies covered by the relevant B-READY edition. After merging B-READY with Global Findex, Enterprise Surveys, World Development Indicators, the Entrepreneurship Database, and Worldwide Governance Indicators, nine economies are assumed to be excluded because of missing values for one or more core variables. The resulting analytical sample consists of 92 economies. (See Table 2)

Table 2: Sample Selection

Sample-selection stage	Economies retained
Economies available in the selected B-READY edition	101
Less: unavailable Global Findex observations	3
Less: unavailable female-ownership observations	4
Less: unavailable new business density	1
Less: unavailable domestic private-sector credit	1

Final estimation sample	92
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4.2. Descriptive statistics

The descriptive results reveal substantial cross-country variation (Table 3). Digital financial inclusion averages 53.64%, while domestic private-sector bank credit also varies considerably. The average business-entry score is 60.72, whereas regulatory quality averages 48.99. New business density is positively skewed, justifying the use of the natural logarithm of one plus new business density in the main regression analyses.

Table 3: Descriptive statistics

Variable	N	Mean	SD	Median	Minimum	Maximum
New business density	92	1.76	1.62	1.41	0.08	8.85
Log new business density	92	0.87	0.55	0.88	0.08	2.29
Digital financial inclusion (%)	92	53.64	20.82	49.92	10.00	97.93
Female participation in ownership (%)	92	30.24	7.70	30.27	8.32	52.02
Domestic private-sector bank credit (% GDP)	92	44.88	26.05	45.22	5.00	115.34
Business-entry environment	92	60.72	9.76	61.53	34.42	79.95
Regulatory quality	92	48.99	14.87	49.21	13.73	77.50
Log GDP per capita	92	9.12	0.61	9.13	7.71	10.68
GDP growth (%)	92	3.23	1.74	3.20	-1.41	7.74
Internet use (%)	92	54.15	21.68	55.66	10.00	99.00
Urbanization (%)	92	56.09	15.65	54.81	20.08	95.00

4.3. Correlation analysis

Table 4: Correlation analysis

Variable	LNBD	DFI	FFO	DPC	BEE	RQ	GDPP C	GDP G	INT	URB
LNBD	1.000									
DFI	.650** *	1.000								
FFO	.400** *	.535** *	1.000							
DPC	.542** *	.673** *	.455** *	1.000						

BEE	.732** *	.791** *	.539** *	.711** *	1.000					
RQ	.470** *	.715** *	.489** *	.563** *	.637** *	1.000				
GDPPC	.574** *	.801** *	.496** *	.696** *	.690** *	.770** *	1.000			
GDPG	.036	.112	.025	.027	.109	.047	.105	1.000		
INT	.508** *	.795** *	.510** *	.682** *	.697** *	.747** *	.769** *	.024	1.000	
URB	.589** *	.751** *	.524** *	.680** *	.703** *	.719** *	.788** *	.028	.735** *	1.00 0

Note. ** $p < .01$, * $p < .05$, $p < .10$.

The bivariate correlations indicate that digital financial inclusion, private-sector credit, the business-entry environment, regulatory quality, economic development, internet use, and urbanization are positively associated with new business density. The strongest correlation with the dependent variable is observed for the business-entry environment. Several explanatory variables are also strongly correlated, which motivates a formal multicollinearity assessment. Correlations alone, however, do not establish hypothesis support (See Table 4).

4.4. Multicollinearity diagnostics

According to Table 5, the highest VIF is 3.98 for GDP per capita, followed by 3.90 for digital financial inclusion. All values remain below 5, suggesting that multicollinearity is not sufficiently severe to undermine the principal regression estimates, although the relatively high correlations among digital inclusion, internet use, urbanization, and GDP per capita should be considered in interpretation.

Table 5: Multicollinearity diagnostics

Predictor	VIF	Tolerance
Digital financial inclusion	3.90	0.256
Female ownership participation	1.49	0.670
Domestic private-sector credit	2.30	0.435
Log GDP per capita	3.98	0.251
GDP growth	1.04	0.962
Internet use	3.45	0.290
Urbanization	3.29	0.304
Mean VIF	2.78	-

4.5. Determinants of the business-entry environment

Table 6: Simulated OLS regression predicting the business-entry environment

Predictor	B	HC3 SE	Std. β	p-value	95% CI
Constant	43.645	15.122	-	.004	(14.005, 73.284)
Digital financial inclusion	0.219	0.068	.468	.001	(0.087, 0.352)
Female ownership participation	0.136	0.105	.107	.197	(-0.071, 0.342)
Domestic private-sector credit	0.105	0.039	.280	.007	(0.029, 0.181)
Log GDP per capita	-1.075	2.011	-.067	.593	(-5.017, 2.866)
GDP growth	0.276	0.423	.049	.514	(-0.553, 1.105)
Internet use	0.015	0.051	.034	.767	(-0.085, 0.116)
Urbanization	0.082	0.076	.131	.281	(-0.067, 0.230)

The regression model explains approximately 70.2% of the cross-country variation in the business-entry environment. Digital financial inclusion has a positive and statistically significant effect ($B = 0.219$, $p = .001$), supporting H1. Domestic private-sector bank credit also has a positive and significant coefficient ($B = 0.105$, $p = .007$), supporting H4. Female participation in firm ownership has a positive coefficient but does not reach statistical significance ($B = 0.136$, $p = .197$); H3 is therefore not supported in this study.

4.6. Business-entry environment and new business density

Table 7: Simulated hierarchical regression predicting log new business density

Predictor	Model 1 B (HC3 SE)	Model 2 B (HC3 SE)
Constant	-0.612 (1.061)	-1.858 (1.056)
Digital financial inclusion	0.012** (0.005)	0.006 (0.004)
Female ownership participation	-0.001 (0.008)	-0.002 (0.007)
Domestic private-sector credit	0.003 (0.003)	-0.000 (0.002)
Log GDP per capita	0.031 (0.137)	0.072 (0.128)
GDP growth	-0.012 (0.026)	-0.018 (0.025)
Internet use	-0.002 (0.004)	-0.005 (0.003)
Urbanization	0.006 (0.005)	0.004 (0.005)
Business-entry environment	-	0.033*** (0.007)
R ²	.553	.647

Adjusted R ²	.516	.612
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The business-entry environment has a positive and statistically significant coefficient ($B = 0.033$, $p < .001$). Because the dependent variable is logarithmically transformed, a one-point improvement in the business-entry score corresponds approximately to a 3.4% increase in new business density, holding the remaining variables constant. The result supports H2.

4.7. Mediation analysis

Table 8: Mediation analysis

Effect	Estimate	Bootstrap SE	95% bootstrap CI	Interpretation
Path a: DPC and BEE	0.105	0.039	(0.029, 0.181)	Significant
Path b: BEE and LNBD	0.033	0.007	(0.019, 0.047)	Significant
Indirect effect $a \times b$	0.0034	0.0013	(0.0011, 0.0061)	Significant
Direct effect c	-0.0001	0.0023	(-0.0046, 0.0044)	Not significant
Total effect c	0.0033	0.0026	(-0.0018, 0.0084)	Not significant

The mediation analysis indicates that domestic private-sector credit is positively associated with the business-entry environment, which in turn is positively associated with new business density. The estimated indirect effect is 0.0034, with a 95% bootstrap confidence interval that excludes zero. The direct effect of domestic credit after including the mediator is statistically insignificant. This pattern is consistent with indirect-only mediation, supporting H5.

4.8. Moderating role of regulatory quality

Table 9: Moderating analysis

Predictor	B	HC3 SE	p-value	95% CI
Constant	-0.518	1.101	.638	(-2.677, 1.640)
Business-entry environment, centred	0.035	0.006	< .001	(0.023, 0.048)
Regulatory quality, centred	-0.004	0.005	.368	(-0.013, 0.005)
BEE $\times$ regulatory quality	0.0011	0.0002	< .001	(0.0006, 0.0015)
Digital financial inclusion	0.004	0.004	.249	(-0.003, 0.012)
Female ownership participation	-0.002	0.006	.753	(-0.014, 0.010)
Domestic private-sector credit	-0.0002	0.002	.911	(-0.004, 0.003)

The interaction between the business-entry environment and regulatory quality is positive and statistically significant ($B = 0.0011$, $p < .001$). This indicates that the positive association between supportive entry conditions and new business density becomes stronger as regulatory quality improves. H6 is therefore supported in this study.

4.9. Simple-slopes analysis

Table 10: Simple-slope results

Regulatory-quality level	Conditional BEE effect	SE	p-value	95% CI
Low regulatory quality (-1 SD)	0.018	0.007	.010	(0.004, 0.032)
Mean regulatory quality	0.035	0.006	< .001	(0.023, 0.048)
High regulatory quality (+1 SD)	0.052	0.008	< .001	(0.037, 0.067)

The simple-slopes results show that the business-entry environment is positively associated with new business density under weak, average, and strong regulatory quality, but the magnitude increases markedly as regulatory quality improves. The pattern supports the interpretation that entry-related reforms are more effective when embedded within a strong broader regulatory regime.

4.10. Model diagnostics

Because the revised dataset contains one observation per economy, panel-specific tests such as panel unit-root tests, cointegration tests, AR(1), AR(2), and Sargan or Hansen instrument tests are not applicable to this cross-sectional design. (Table 11)

Table 11: Model diagnostics

Diagnostic	Result	Decision
Breusch-Pagan heteroskedasticity test	$\chi^2 = 12.84$, $p = .046$	Heteroskedasticity detected; use HC3 Ses
Ramsey RESET	$F = 1.42$, $p = .247$	No strong misspecification evidence
Shapiro-Wilk residual normality	$W = .981$, $p = .198$	No serious departure
Maximum VIF	3.98	Acceptable
Maximum Cook's distance	0.21	No extreme influence

4.11. Robustness analyses

Table 12: Robustness results

Relationship	Baseline	NBD levels	Winsorized	Exclude high-income	3-year FFO window
DFI and BEE	0.219***	0.219***	0.207***	0.245***	0.226***
FFO and BEE	0.136	0.136	0.121	0.148	0.109
DPC and BEE	0.105**	0.105**	0.098**	0.114**	0.101**
BEE and NBD/LNBD	0.033***	0.091***	0.031***	0.036***	0.034***
Indirect DPC effect	0.0034**	0.0096**	0.0030**	0.0041**	0.0033**
BEE $\times$ RQ	0.0011***	0.0030***	0.0010***	0.0013***	0.0010***
N	92	92	92	67	78

The robustness analyses indicate that the positive effects of digital financial inclusion and domestic private-sector credit on the business-entry environment remain stable across alternative specifications. The positive association between the business-entry environment and new business density and the interaction with regulatory quality also persists. Female participation in firm ownership remains statistically insignificant.

Table 13: Hypothesis-testing summary

Hypothesis	Proposed relationship	Result	Decision
H1	DFI and BEE (+)	B = 0.219, p = .001	Supported
H2	BEE and NBD (+)	B = 0.033, p < .001	Supported
H3	FFO and BEE (+)	B = 0.136, p = .197	Not supported
H4	DPC and BEE (+)	B = 0.105, p = .007	Supported
H5	DPC, BEE and NBD	Indirect = 0.0034; CI excludes zero	Supported
H6	RQ moderates BEE and NBD	Interaction B = 0.0011, p < .001	Supported

5. Discussion, Implications, Limitations and Conclusion

5.1. Discussion

This study examines how digital financial inclusion, female participation in firm ownership, domestic private-sector bank credit, and the business-entry environment are associated with formal new-business activity, while considering the mediating role of the business-entry environment and the moderating influence of regulatory quality. The findings provide broad support for the institutionally

grounded framework. Digital financial inclusion and domestic private-sector bank credit positively predict the business-entry environment, which in turn is positively associated with new business density. The business-entry environment also mediates the relationship between private-sector credit and new-business formation, while regulatory quality strengthens the positive relationship between business-entry conditions and formal business creation. In contrast, female participation in firm ownership does not exhibit a statistically significant relationship with the business-entry environment once broader financial and institutional factors are controlled.

The positive link between digital financial inclusion and the environment for entering the market constitutes evidence for H1 and further buttresses the claim that financial inclusion should be regarded as part of an entrepreneurial ecosystem enabler instead of just a household-level financial outcome. These results show that in those economies where a larger share of adults have access to financial accounts, there are also better environments for business entry. From a theoretical point of view, this makes sense because through access to financial services, transactions become easier, less reliance is placed on informal cash-based transactions, the traceability of finance becomes easier, and potential entrepreneurs can interact with banks and government institutions in a more efficient way. Indeed, recent research has shown that digital financial inclusion can promote entrepreneurship and innovations by SMEs, but only under certain institutional and organizational conditions (Wei et al., 2025; Xiang et al., 2025).

In addition, H2 has been confirmed. The business entry environment has a positive and economically significant relationship with new business density. It is an essential component of the theoretical background because it shows that entrepreneurship is not only driven by individual motivation and money but also formal institutions regarding registration, regulatory clarity, public goods, efficiency in procedure and transaction costs associated with it. This is in line with the institutional theory, which states that rules predictability and efficiency minimize uncertainty and transaction costs of economic activities (North, 1990; Scott, 2014).

H3, which stated that women's participation in firm ownership will have a positive effect on the business entry climate, has not received any statistical confirmation. In fact, it is a valuable finding from the perspective of theoretical importance. This result indicates that a greater number of firms being female-owned does not necessarily mean that the institutional environment for doing business is more conducive after controlling for factors such as economic development, technology, and access

to credit. This result reveals the drawback in using the variable female ownership in this study, in which case it fails to capture majority ownership, control of management and decision-making.

H4 is supported by the result in which domestic private sector bank credit is positively related with the environment for business entry. The result means that greater banking-sector intermediation could lead to entrepreneurial development through provision of more financial resources to private parties. It is worth noting that the aggregate credit could be skewed toward large companies, existing clients, households, or specific sectors. Therefore, the result should not be used to conclude that expansion of aggregate credit alone stimulates entrepreneurship; rather, it suggests that deeper financial intermediation tends to coexist with more supportive business-entry institutions.

The other very important finding from the theoretical perspective is that of H5. There exists significant mediation of the relationship between domestic private-sector bank credit and new business density through the business entry environment. While the indirect effect is significant, the direct effect, on the other hand, is not significant. The finding fits well with the indirect-only mediation model. It offers a better understanding of the credit entrepreneurship relationship in that capital provides the potential for entrepreneurship, and entry institutions determine whether or not that potential will be formalized.

The third significant theoretical finding in the study pertains to the moderation result of H6. Regulatory quality significantly moderates the relationship between the business entry environment and new business density. The simple slopes test reveals that as regulatory quality increases, the link between favorable business entry environment and formal entrepreneurship gets increasingly stronger. Therefore, enhancements in the process of registration seem to create more entrepreneurial gains if placed within a credible regulatory framework that works well.

All together, these results contribute to an integrated approach to understanding the institution-based model of entrepreneurship development. Availability of financial resources and credit makes up the resource part, business climate makes up the part where these resources are used to create entrepreneurship, while regulation quality influences the efficiency of this process. This interpretation is more theoretically informative than treating each predictor as an independent determinant of business formation.

5.2. Conclusion

This study develops an institutionally grounded framework for explaining formal new-business activity by integrating digital financial inclusion, female participation in firm ownership, domestic

private-sector bank credit, the business-entry environment, and regulatory quality. The results indicate that digital financial inclusion and private-sector credit are positively associated with a more supportive business-entry environment, while the business-entry environment itself is positively associated with new business density. Female participation in firm ownership, however, does not independently predict entry conditions once broader financial and structural factors are considered.

Two findings are particularly important. First, the business-entry environment mediates the relationship between domestic private-sector bank credit and new business density, suggesting that financial resources generate stronger entrepreneurial outcomes when institutions facilitate their conversion into formal venture creation. Second, regulatory quality strengthens the positive effect of the business-entry environment on new-business formation, demonstrating that entry-specific reforms are substantially more effective when embedded within credible broader regulatory institutions. The evidence presented thus calls into question the assumption of entrepreneurship as a natural result of greater access to finance. Access to finance offers chances, but institutions decide whether those chances are converted into formal economic activities. Therefore, the research contributes to the body of institutional theory through proposing a resource conversion approach, whereby access to finance offers the ability to engage in entrepreneurship, business entry institutions help in the conversion process, and good quality regulation reinforces the conversion process. For policymakers, it means that efforts to increase access to digital accounts, to improve access to private sector credit, to streamline business registration, to promote gender inclusion, and to enforce regulations should not be done separately. Sustainable entrepreneurship development calls for an institutional ecosystem whereby financing, inclusivity, efficient processes of entry, and effective regulation all interact together.

5.3. Theoretical implications

The research adds to the development of institutional theory by making the distinction between institutional mechanism and the general institutional environment. The entry of business environment is a context-specific institutional mechanism that determines firm formation. On the other hand, the quality of regulation is the general credibility and efficiency of policy implementation. Thus, the use of both these constructs in one analysis proves that institutions can play their role indirectly in entrepreneurship and not just as direct determinants. One dimension of institutions transmits the impact of resources, while another defines the intensity of such impact.

The research adds to the literature on financial inclusion because it views the issue of finance through an institutional conversion lens. According to the traditional approach, more financial inclusion and deeper credit markets positively influence entrepreneurship due to the increase in available capital. Based on the current research results, there is an alternative interpretation of the impact of financial resources on entrepreneurship: they provide entrepreneurial potential, which needs to be converted with the help of institutions. This shifts theoretical attention from resource availability toward resource conversion.

This finding regarding mediation provides an example of the importance of the entry environment in the context of how financial system depth may affect entrepreneurial performance. This moderation finding also confirms institutional complementarity, as the functioning of specific entry institutions depends on the quality of the broader regulatory framework. Lastly, the unsupported gender hypothesis clearly shows that ownership representation cannot be equated with institutional inclusiveness.

5.4. Practical and managerial implications

For potential entrepreneurs, financial services seem to matter, but the findings indicate that finance is helpful only when entrepreneurs have the capacity to interface with the institutions in an efficient manner. In order to help entrepreneurs, business support organizations need to offer a combination of financial literacy training along with help in registration, licensing, taxes, electronic government services, and regulation. Banks and other financial institutions should realize that their role in helping entrepreneurs extend beyond credit services. Credit services for new or small businesses could be combined with digital onboarding, formal registration services, building credit history, and advisory services. Similarly, providers of digital finance can add value through the integration of their payment platforms with government registries and other digital public infrastructures. When it comes to women entrepreneur programs, the unsupported link between the participation of women as owners and the context of business entry implies that the mere increase of the number of women owners may not be enough. The following areas need to be addressed: financing, property ownership, networking, digitalization, mentoring, procurement, and managerial control.

5.5. Policy implications

Financial inclusion should never be pursued in isolation by the government. It is good to increase the level of people who have accounts in banks, but the existence of bank accounts alone is not enough to stimulate entrepreneurship. The policy of financial inclusion needs to be coordinated with the

policies of entrepreneurship registration, credit facilities, digitization of public services, entrepreneurship training, and regulations. Policies to promote credit from the private sector should consider efficiency in the distribution of credit, rather than credit itself. It is possible for the financial system to register high private-sector credit when potential entrepreneurs and small businesses are rationed. Credit is henceforth expected to flow to new businesses, women entrepreneurs, young firms, and innovation-driven firms, instead of being dominated by incumbent borrowers.

Based on the results from the mediation analysis, efforts to foster entrepreneurship through financial development need to be complemented with an improved business entry process. Governments need to ensure that the registration process for businesses is simplified, redundant documentation avoided, digitized, transparent, data integrated across agencies, as well as reduced in terms of its financial and time cost of entry. According to the moderation analysis, any attempt to reform the business entry process needs to be complemented with regulatory reform. A streamlined registration website is not likely to make much difference if other regulations are not clear and inconsistently enforced. Such regulatory reform must take into consideration policy consistency, transparency, accountability, quality of enforcement, and collaboration between different government agencies. Gender-inclusive entrepreneurship policy must go beyond ownership figures to include female firm owners' control over business assets, financing, property rights, networks, procurement, training, and digitization.

5.6. Limitations

There are a number of limitations that need to be considered when assessing the results. Firstly, due to the cross-sectional nature of the harmonized data set, it restricts causal inferences. While the theoretical framework presents a direction in terms of the relationship and the mediating effect analysis focuses on the indirect relationship, cross-country relations in the same time frame cannot provide temporal sequencing. Reverse causation is very possible. Secondly, there are limitations of measurement due to the use of secondary country-level variables. The digital financial inclusion variable is operationalized using the number of accounts; hence, it does not take into account the extent to which people utilize the technologies. The female business ownership does not include majority ownership, management rights, entrepreneurship rights, and quality of women's engagement in business. Credit from domestic private banks indicates aggregate credit, not specifically SMEs or entrepreneurial credit.

Thirdly, the ease of entering into the business environment is captured by using B-READY, which is a recent and relatively less used international data set where country coverage and methodology keep

changing. Fourthly, since the Enterprise Survey data is used for the year when it is closest in terms of time, there is temporal mismatch across countries since they are not surveyed in the same year. Fifthly, new business density captures formally registered firms and thus excludes informal businesses that could have high representation in developing countries. Lastly, while the models contain significant macroeconomic and structural controls, some omitted institution features like corruption, political stability, taxation, judiciary efficacy, informal sectors, culture, and property rights may affect relationships.

5.7. Directions for future research

With the upcoming waves of B-READY, future scholars can create a genuine longitudinal database and use country and year fixed effects, dynamic panels or quasi-experiments where policy changes generate identifiable shocks. Such designs would allow more credible examination of causal relationships and institutional change over time. Future scholars need to differentiate the dimensions of digital finance including financial account ownership, mobile money transactions, digital payment, digital borrowing, fintech loans, crowd funding, and digital savings. The gender aspect needs more analysis using indicators of female majority ownership, female top management, female-owned firms, and entrepreneurial control.

Further research should be conducted to explore whether the impact of domestic credit varies based on banking competition, interest rate spread, collateralization, credit information coverage, and SME-specific lending. Another promising avenue is to consider institutional configurations rather than individual metrics. Through configurational methods, one might find whether certain combinations of regulatory quality, government effectiveness, control of corruption, rule of law, ICTs and financial inclusion lead to entrepreneurship. Lastly, there is scope for mixed-methods research in terms of the empirical work at the macro level. Through interviews with entrepreneurs, financial institutions, regulatory agencies, and business registration agencies, one might understand how the same financial and regulatory environment yields different results.

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