Evaluating the Diagnostic Accuracy of a Screening Questionnaire for Detecting Hidradenitis Suppurativa: A Pooled Analysis of Accuracy Measures from the Global Hidradenitis Suppurativa Atlas (GHiSA) Study

Running head: Diagnostic accuracy of GHiSA screening questionnaire

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What is already known about this topic?

- Hidradenitis Suppurativa (HS) is a devastating inflammatory skin disease with a prolonged diagnostic delay of approximately 7–10 years, often due to low awareness among non-dermatologic healthcare professionals leading to misdiagnosis.

- Screening questionnaires have been proposed to aid diagnosis, and one such tool has been validated and used in the Global Hidradenitis Suppurativa Atlas (GHiSA) Global Prevalence Study (GPS).

What does this topic add?

- The pooled analysis indicated that the accuracy was excellent for the GHiSA screening, with a pooled sensitivity of 0.88 and a pooled specificity of 0.86.
- The screening questionnaire may prove useful in triaging, ensuring that only individuals fitting the criteria see specialized dermatological care.

ABSTRACT

Background: Hidradenitis Suppurativa (HS) is a devastating inflammatory skin disease with a prolonged diagnostic delay of approximately 7-10 years. The diagnostic delay can be attributed to varying factors, including low awareness of diagnostic criteria among non-dermatologic healthcare professionals often leading to misdiagnosis. Screening questionnaires have been proposed for the diagnosis of HS, and one of such has been validated and used in the Global Hidradenitis Suppurativa Atlas (GHiSA) Global Prevalence Study (GPS).

Objective: To evaluate and provide a summary of the diagnostic accuracy measures (pooled sensitivity and specificity) of the screening questionnaire employed in the GHiSA GPS.

Methods and Materials: All studies that adhered to the GHiSA methodology and provided diagnostic accuracy data were eligible for inclusion. The data was extracted from the eligible studies and typed into an excel sheet twice by two authors. Data on geographical location and diagnostic accuracy parameters (true positive, false positive, true negative and false negative) were extracted from the included studies. The quality of the included studies were assessed using

the quality assessment of diagnostic accuracy studies tool (QUADAS-2).

Results: Data from 25 studies (23 countries) were included in the pooled analysis. The QUADAS-2 assessment revealed high risk of bias in the domains "reference standard" and "patient flow". For applicability, there were concerns for "patient selection". Substantial variations in sensitivity (0.43– 1.00) and specificity (0.15 -1.00) values were observed globally. The bivariate random effects model showed a pooled sensitivity of 0.88 (95%CI; 0.80 to 0.94) and a pooled specificity of 0.86 (95%CI; 0.78 to 0.91). The summary operating receiver curve (sROC) revealed a clustering of studies in the upper left corner, indicating a sensitivity and specificity close to one. The area under the curve (AUC) was 0.93, suggesting excellent accuracy.

Conclusion: Despite substantial variations in the diagnostic estimates across the globe, the pooled analysis indicated that the accuracy was excellent for the GHiSA screening questionnaire. The screening questionnaire may prove useful in triaging, ensuring that only individuals fitting the criteria see specialized dermatological care.

INTRODUCTION

Hidradenitis Suppurativa (HS) is a devastating inflammatory skin disease. (1) Patients commonly present with nodules, abscesses and tunnels that can progress into significant scarring. HS patients frequently describe associated severe pain, malodorous discharge, and pruritus. (2) Patients also suffer from a decreased quality of life, impactful comorbidities, and a higher all-cause mortality. (3-5) Given these factors, early diagnosis and effective treatment become imperative. (6) The diagnosis of HS represents a crucial initial step in managing the condition. However, the global diagnostic delay has been reported to be 7-10 years for HS patients. (7, 8)

The global diagnostic delay can be attributed to varying factors, including low awareness of diagnostic criteria among non-dermatologic healthcare professionals (9), misdiagnosis, flawed perception of HS, non-white race, and stigmatization of affected individuals. (6, 8-10)

The current reference standard for diagnosing HS is a clinical evaluation of the lesions and a characteristic history, involving the following: typical lesions occurring in one or more of the predilection sites, and the patients reporting of reoccurrence of symptoms. (11-13) The above-mentioned clinical criteria frequently require the involvement of a dermatologist, given the high risk of misdiagnosis. This poses a significant challenge in major parts of the world, where access to dermatological care is severely restricted. (14-16) Additionally, the clinical assessment can be time-consuming, and evaluating intimate areas may be difficult for patients. (6) Other simpler methods to diagnose or screen for HS have been proposed, including the usage of clinical diagnostic tools such as screening questionnaires. One of such has been developed by Vinding and Esmann et al (17, 18), and validated globally as a part of the Global Hidradenitis Suppurativa Atlas (GHiSA) Global Prevalence Studies (GPS). (19-22) The uniformity in the methodological approach maintained across the GHiSA GPS presents a unique opportunity to evaluate the diagnostic accuracy of the screening questionnaire (index test) in different languages and countries.

Using a screening questionnaire for future triage can help clinicians worldwide, including those with limited access to dermatologists, to enhance diagnostic decision making and potentially reduce the current global diagnostic delay. The objective of this study was therefore to summarize and evaluate the diagnostic accuracy of the screening questionnaire employed in the GHiSA GPS for detecting HS in healthy adults accompanying patients to the hospital. This entailed evaluating the essential diagnostic test accuracy parameters sensitivity and specificity.

METHODS AND MATERIALS

Eligible criteria

To maintain a high level of consistency and accuracy in the pooled results, only studies that adhered to the standardized GHiSA method developed by Bouazzi D. et al (22) were eligible for inclusion. This entailed studies that investigated the prevalence of HS (target condition) among apparently healthy adults (>18 years of age) accompanying patients undergoing care at an hospital or private/family medicine clinics using a screening questionnaire (index test) first developed by Vinding et al. (17) All apparently healthy accompanying adults who consented to participate were eligible for inclusion. Exclusion criteria included pregnant women, individuals unable to provide informed consent (e.g., minors), and previously enrolled participants. Departments of dermatology were also excluded as possible recruitment sites. The questionnaire contains two simple questions: *"Have you had outbreaks of boils during the last 6 months' and ii) 'Have you for the past 6 months had 2 or more boils/abscesses in any of the below locations with five different location options [axilla, groin, genitals, under the breasts and other locations (not specified), e.g., perianal, neck and abdomen]". (17, 22)* A participant screened positive if they answered yes to both of the abovementioned screening questions. All screen positives and approximately ten percent of the screen negatives were instructed to receive the reference standard (i.e., clinical examination by an HS-trained physician). Moreover, only studies that had finalized the data collection prior to 2023.05.19 were eligible for inclusion. Finally, studies that adhered to the GHiSA protocol but failed to produce diagnostic accuracy data (two by two tables, i.e. number of false positives, false negatives, true positives, and true negatives) were excluded from this pooled analysis. This rigorous approach was taken to minimize the heterogeneity and

ensure reliability and accuracy of the data. Only studies written in English were considered for inclusion. A separate ethical approval was not required for this pooled analysis.

Data collection process

The data was extracted from the eligible studies and typed into an excel sheet twice by two authors (DB and CEM). The extracted data were compared, and any discrepancies resolved through double checking or discussion. In instances where essential information was unclear, the authors were contacted in order to obtain the additional information.

Data extraction and definitions

A true positive (TP) was considered a diagnosis of HS in a healthy adult, indicated by a positive outcome on the index test (screening questionnaire) and subsequently confirmed by the reference standard (clinical examination by an HS-trained physician). A true negative (TN) was considered as a healthy adult without HS, confirmed by a negative outcome on the index test as well as for the subsequent reference standard. A false positive (FP) was characterized by a positive outcome on the index text and a subsequent absence of HS through the reference standard. Finally, a false negative (FN) was defined as a negative result on the index test, while HS was identified through the reference standard. The following data were extracted from the included studies: geographical location (country, and continent), number of TP, FN, FP, TN. These measures were retrieved from the included diagnostic cross-tabulations. Finally, the following information was also extracted: sensitivity/specificity values including confidence intervals, and positive and negative predictive values including confidence intervals.

Risk of bias and applicability

The quality of the included studies were assessed using the *quality assessment of diagnostic accuracy studies* tool (QUADAS-2). (23) QUADAS 2 is designed to explore the bias and applicability of diagnostic accuracy studies. It is comprised of four key domains: patient selection, index test, reference standard, and flow and timing. The studies were rated as low, high, or unclear risk and presented as a singular result, given that all studies adhered to the same methodology and approach.

Diagnostic accuracy measures

The data extracted from the collected diagnostic cross-tabulations were utilized to compute sensitivity and specificity for each country. The individual countries were visually represented through the depiction of sensitivity and specificity estimates, along with their corresponding 95% confidence intervals (95% CIs), calculated as exact intervals (23). The bivariate random effects meta-analysis model as implemented in the *mada* package in R (version 4.3.1) was used to combine the sensitivity and specificity proportions. The model acknowledged the assumption that variability among studies could not be attributed to chance only, and it accounted for a correlation between sensitivity and specificity. The sROC curve was plotted to visualize the trade-off between sensitivity and specificity across countries. After model fitting, the estimated parameters of the means and covariance matrix of the logit-transformed sensitivity and specificity were extracted. The sROC curve was generated by transforming the estimated parameters back to the original scale for sensitivity and specificity, i.e. by first calculating the

mean sensitivity and specificity on the logit scale, and then using the inverse logit transformation to convert these back to the probability scale.

The calculation of the area under the curve (AUC) was based on the fitted curve. AUC values ranged from 0-1, with values >0.9 indicating excellent accuracy, and values <0.6 indicating poor accuracy. (24, 25)

RESULTS

A total of 74 countries were invited to participate in the GHiSA GPS. Due to varying reasons including failure to initiate, finalize or obtain ethical approval, a total of 51 countries were excluded. Finally, studies conducted in a total of 23 countries (25 studies) (19, 20, 26-48) were included in the final pooled analysis. **Figure 1** illustrates the flow diagram, with a visual representation of the included countries (studies), which depicts a flowchart of the selection process.

Study characteristics

The study characteristics are summarized in **Table 1** for all eligible studies. All the included studies employed the same index test and reference standard. The sampled population across all the studies were healthy adults accompanying a patient to the outpatient clinics of a hospital or private/family medicine clinics, excluding the department of dermatology. The percentage of screen-negatives that were clinically assessed varied from 0.4% to 36.2%. The diagnostic estimates varied across the included studies. The sensitivity varied from 0.43– 1.00 and

specificity from 0.15 -1.00. Studies from a total of 19/23 countries exhibited a sensitivity >90%. The positive and negative predictive values are also presented in Table 1. The PPV varied from 0.05-1.00 and the NPV from 0.97-1.00. A total of 17/23 countries exhibited an NPV of 1.00.

Risk of bias and applicability results

Supplementary table 1 present the results of the QUADAS-2. The risk of bias was low for the domains "patient selection" and "index test". For the domain "reference standard", the risk of bias was rated high, due to the fact that the reference standard was interpreted with the knowledge of the index test (i.e., possible presence of verification bias). The patient flow (domain 4) also introduced high risk of bias, due to the fact that not all participants received the reference standard and therefore not all were included in the final analysis (i.e., only approximately ten percent of the screen negatives received the reference standard). For applicability, there were only concerns for patient selection (domain 1), due to potential selection bias.

Pooled analysis of diagnostic accuracy data

Figure 2 displays a paired forest plot of the sensitivity and specificity for each included country together with CIs and the 2×2 diagnostic test accuracy tabular data. The bivariate random effects model of 23 countries, originating from 25 studies revealed a pooled sensitivity of 0.88 (95%CI; 0.80 to 0.94) and a pooled specificity of 0.86 (95%CI; 0.78 to 0.91). The summary receiver operating curve (sROC) displayed in **Figure 3** visually illustrates the variations in accuracy across the included studies. The figure also features the summary point, a fitted line, and a reference line of no discrimination. Each data point on the plot corresponded to a study conducted in a specific country. Notably, the majority of the studies exhibited a clustering

pattern in the upper left corner of the ROC space, indicating a sensitivity and specificity close to 1. All the studies were above the diagonal line, which represented the line of no-discrimination. The area under the curve (AUC) was calculated to be 0.93. This suggested excellent accuracy.

DISCUSSION

The objective of this study was to provide a pooled analysis of the diagnostic accuracy measures (sensitivity and specificity) of the screening questionnaire employed in the GHiSA GPS study. We exclusively included studies from the GHiSA GPS study to ensure uniformity in study design, study population and diagnostic threshold, therefore minimizing any potential variability arising from these factors. The results demonstrate a high diagnostic accuracy (pooled sensitivity 0.88 and specificity 0.86) of the screening questionnaire in detecting HS in healthy adults accompanying patients to the hospital. For comparison, one study reported that standard mammography, a commonly used breast cancer screening tool, has a sensitivity of 60%, a specificity of approximately 80%, and an AUC of 0.73. (49) The specificity of 0.86, coupled with high NPV values and comparably lower PPV values indicate that the test is proficient in detecting true negatives, but the possibility of false positive suggest caution in relying solely on the screening questionnaire to determine a final diagnosis, meaning it should not replace clinical assessment. (50) However, the screening questionnaire could serve as valuable role in triaging or screening, ensuring that only individuals identified as screen positives undergo assessment by a dermatologist. This approach is especially beneficial in regions with limited access to specialized dermatology care. Moreover, the simplicity, speed, and cost-effectiveness of the two-question screening questionnaire makes it a practical tool for use in primary-care setting, where

knowledge about HS may be limited. (16, 51)

In our study, we observed substantial differences in sensitivity and specificity estimates across the included studies, as illustrated in both forest plot and the scatter in the sROC. While this is commonly attributed to factors such as heterogeneity in study design, diagnostic threshold, and populations, it is noteworthy that these factors were minimal in our study, due to the exclusive inclusion of GHiSA studies. One explanation for the observed variations in our study can be the diverse cultural contexts in which the studies were conducted, with screening questionnaires being administered in different languages. Cultural interpretations and translations of symptoms may have introduced inaccuracies in patient-reported data, potentially affecting the sensitivity and specificity. Moreover, a significant variability in screen negatives receiving the reference standard and the overall sample size across countries was also observed. Some countries had small sample sizes and a low percentage of screen negatives receiving the reference standard, <10% (i.e., China, Saudi Arabia and The Netherlands), raising concerns about reliability and potential sampling bias. Additionally, the operator-dependent nature of the reference standard introduces an additional layer of complexity, as various individuals conducted the reference standard assessments. Although the assessors underwent training to identify HS, the possibility of misclassification bias still remains. Finally, the assessors were not blinded to the status of the index test, leading to potential observer bias, which could also impact the sensitivity and specificity results.

This study has several potential limitations. The narrow inclusion of studies and countries exclusively through the GHiSA study may limit the generalizability of the findings. This limitation is particular evident in the high concern about the applicability of our results to a broader population, including children. Although the decision to exclusively include GHiSA

studies has its merits, it introduces the potential for selection bias, and therefore a risk that the external validity is compromised. Moreover, the high risk of bias in the QUADAS-2 domains "reference standard", and "flow and timing" further lowers the validity the study. Another limitation is the absence of likelihood ratios in the pooled analysis. This prohibits us from making a more comprehensive assessment of the diagnostic test, particularly in the context of clinical decision-making.

Nevertheless, the study also possesses various strengths. A great advantage lies in the methodological consistency observed across the included studies. Additionally, this study presents the first and most extensive pooled analysis, with the aim of offering robust sensitivity and specificity estimates of the GHiSA screening questionnaire. Finally, the inclusion of an international cohort, and the validation of the screening questionnaire in multiple languages, enhances the international applicability of the results.

In conclusion, this analysis estimated a pooled sensitivity and specificity of 0.88 and 0.86. Substantial variations in the estimates were observed globally. The screening questionnaire may prove useful in triaging, ensuring that only individuals fitting the criteria see specialized dermatological care. Ongoing studies within the GHiSA Group are currently focused on expanding the use of the screening questionnaire as a part of the "*Grand Challenges of the Skin Health"*. (52)

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Figure legends

Figure 1: Flowchart of included countries

Flow diagram illustrating the inclusion and exclusion process of countries included in the final pooled analysis. Initially, 74 countries were invited to participate in the Global Hidradenitis Suppurativa Atlas (GHiSA) Global Prevalence Studies. Only studies from countries that had finalized the data collection prior to 2023.19.05 were eligible for inclusion.

Figure 2: Bivariate random effect model of sensitivity and specificity of the GHiSA screening questionnaire

This forest plot displays a bivariate random effects model for sensitivity and specificity measures, encompassing data from all the included countries. Additionally, this plot includes pooled estimates for both sensitivity and specificity. CI: confidence interval, TP: True positive, FP: False positive, FN: False negative TN: True negative.

Figure 3: Summary Receiver Operating Curve (sROC) across included countries (studies)

This plot illustrates a summary receiver operating curve using data points corresponding to different countries. The x-axis represents the false positive rate, while sensitivity is depicted on the y-axis. The plot features a fitted line, line of no discrimination and summary point.

Table 1: Characteristics of the included studies

Country	Continent	Cases with HS (n)	Total screened (n)	True Positive (TP)	False Positive (FP)	False Negative (FN)	True Negative (TN)	% screen negatives clinically assessed *	Sensitivity (CI)	Specificity (CI)	PPV (CI)	NPV (CI)
Algeria(26)	Africa	11	1,434	11	18	0	508	36.2	1.00 (0.72-1.00)	0.97 0.95 - 0.98	0.38 (0.21– 0.58)	1.00 (0.99-1.00)
Australia (27)	Oceania	9	1,002	9	0	0	48	4.8	1.00 (0.66-1.00)	1.00 0.93- 1.00	1.00 (0.66-1.00)	1.00 (0.93-1.00)
Bangladesh (28)	Asia	3	2,377	3	0	0	23	1.0	1.00 (0.29-1.00)	1.00 0.85- 1.00	1.00 (0.29-1.00)	1.00 (0.85-1.00)

Chile (29)	Latin America and the Caribbean	12	500	12	8	0	50	10.4	1.00 (0.74-1.00)	0.86 0.75- 0.94	0.60 (0.36-0.81)	1.00 (0.93-1.00)
China (30)	Asia	2	552	2	2	0	2	0.4	1.00 (0.16-1.00)	0.50 0.07- 0.93	0.50 (0.07-0.93)	1.00 (0.16-1.00)
France (31)	Europe	18	525	18	11	0	48	9.7	1.00 (0.81-1.00)	0.81 0.69- 0.90	0.62 (0.42-0.79)	1.00 (0.93-1.00)
Ghana(20, 32)	Africa	14	1,988	14	35	0	194	10.0	1.00 (0.77-1.00)	0.85 0.79- 0.89	0.29 (0.17-0.43)	1.00 (0.98-1.00)
Greece (33)	Europe	1	553	1	19	0	60	11.3	1.00 (0.03-1.00)	0.76 0.65- 0.85	0.05 (0.00-0.25)	1.00 (0.94-1.00)
Greenland(19)	Northern America	16	506	16	27	0	54	11.7	1.00 1.00- 1.00	0.67 0.56- 0.77	0.37 (0.23-0.52)	1.00 (1.00-1.00)
Indonesia (34)	Asia	14	3,237	6	24	8	362	11.5	0.43 0.18- 0.71	0.94 0.91- 0.96	0.20 (0.08-0.39)	0.98 (0.96-0.99)
Iran (35)	Asia	3	990	3	19	0	97	10.0	1.00 (0.29-1.00)	0.83 0.76- 0.90	0.13 (0.03-0.35)	1.00 (0.96-1.00)
Malaysia (48)	Asia	7	500	7	3	0	49	10.0	1.00 0.59- 1.00	0.94 0.84- 0.99	0.70 (0.35-0.93)	1.00 (0.93-1.00)
Nigeria (36, 37)	Africa	51	1,700	49	13	2	139	8.6	0.96 0.87- 1.00	0.91 0.86- 0.95	0.79 (0.67-0.88)	0.99 (0.95-1.00)
North Macedonia (38)	Europe	5	597	3	13	2	66	11.7	0.60 0.15- 0.95	0.84 0.74- 0.91	0.19 (0.04-0.46)	0.97 (0.9-1.00)
Oman (39)	Asia	10	484	10	19	0	51	11.2	1.00 0.69- 1.00	0.73 0.61- 0.83	0.34 (0.18-0.54)	1.00 (0.93-1.00)
Papua New Guinea (40)	Oceania	2	520	1	0	1	118	22.9	0.50 0.01- 0.99	1.00 0.97- 1.00	1.00 (0.03-1.00)	0.99 (0.95-1.00)
Poland (41)	Europe	15	932	14	7	1	99	11.0	0.93 0.68- 1.00	0.93 0.87- 0.97	0.67 (0.43-0.85)	0.99 (0.95-1.00)
Saudi Arabia (42)	Asia	28	688	28	40	0	7	1.1	1.00 0.88- 1.00	0.15 0.06- 0.28	0.41 (0.29-0.54)	1.00 (0.59-1.00)
Serbia (43)	Europe	4	490	2	5	2	62	13.3	0.50 0.07- 0.93	0.93 0.83- 0.98	0.29 (0.04-0.71)	0.97 (0.89-1.00)
South Africa (44)	Africa	9	500	9	13	0	51	10.7	1.00 0.66- 1.00	0.80 0.68- 0.89	0.41 (0.21-0.64)	1.00 (0.93-1.00)
Sri Lanka (45)	Asia	2	993	2	0	0	96	9.7	1.00 0.16- 1.00	1.00 0.96- 1.00	1.00 (0.16-1.00)	1.00 (0.96-1.00)
The Netherlands (46)	Europe	4	663	4	6	0	14	2.1	1.00 0.40- 1.00	0.70 0.46- 0.88	0.40 (0.12-0.74)	1.00 (0.77-1.00)
Türkiye (47)	Asia	7	1,012	7	28	0	110	11.2	1.00 0.59- 1.00	0.80 0.72- 0.86	0.20 (0.08-0.37)	1.00 (0.97-1.00)

Key characteristics of included studies, encompassing details such as geographical location, and diagnostic accuracy measures (sensitivity, specificity, positive predictive values, and negative predictive values). Additionally, the table includes number of true positives, false positives, true negatives, and false negatives.

* Indicates the percentage of screen negative participants clinically assessed (i.e., receiving the reference standard).

HS: Hidradenitis Suppurativa, CI: Confidence interval, PPV: Positive predictive value, NPV: Negative predictive value

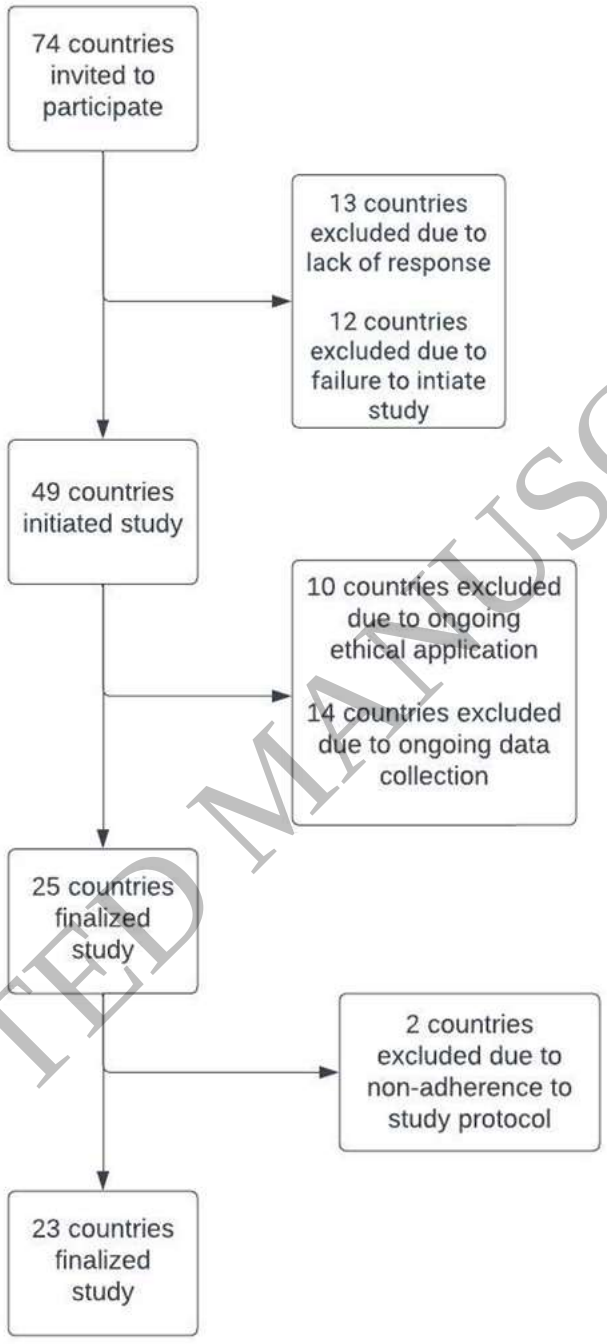

Figure 1
91x188 mm (x DPI)

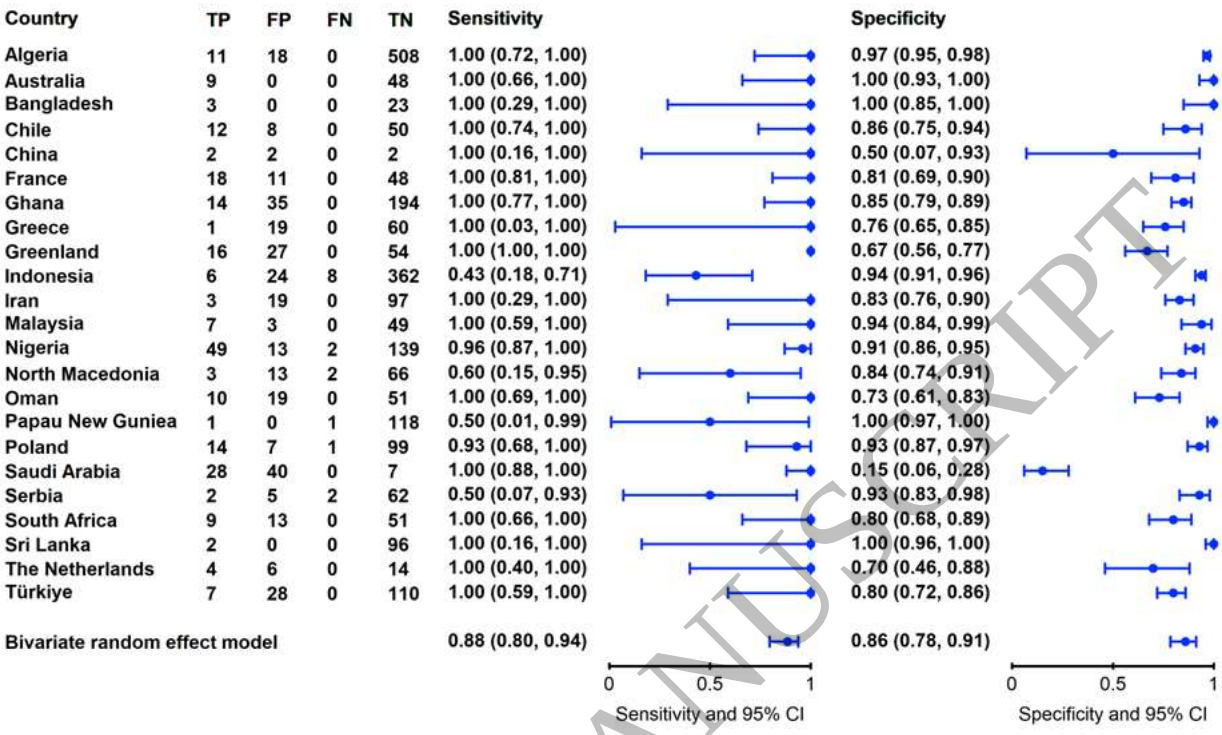

Figure 2
170x97 mm (x DPI)

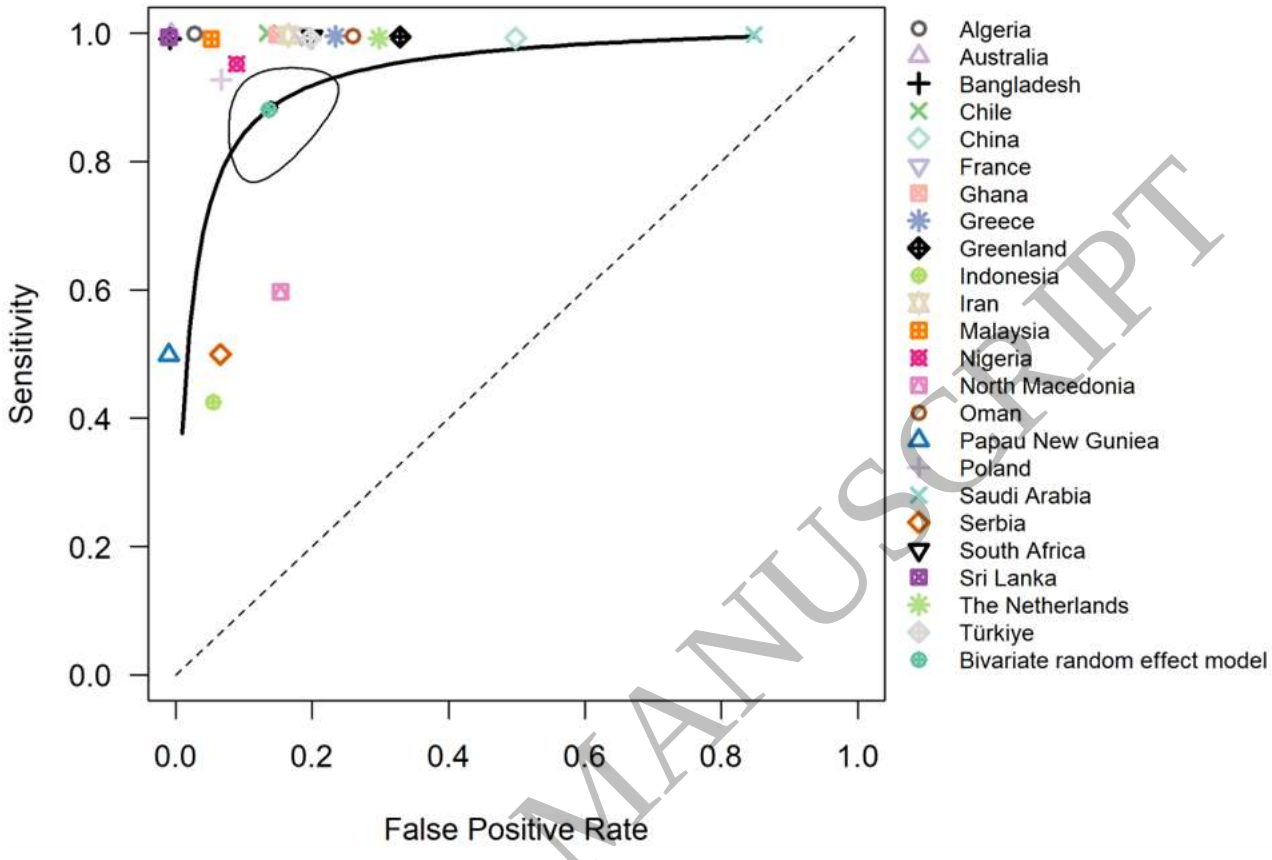

Figure 3
170x116 mm (x DPI)

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(n=265/349)

of patients with PsO achieved **PASI 75 at Week 4**

(vs 1.2% placebo [n=1/86], p<0.0001)*,**[2]

76.9%
(N=52)†

of patients with PsO achieved **PASI 100 at 5 years**[3]

51.5%
(n=222/431)

and

50.6%
(n=135/267)

of biologic-naïve and TNFi-IR PsA patients achieved **ACR 50 at Week 104/100,** respectively‡[1,4–6]

BIMZELX was well tolerated, the most frequently reported adverse reactions were: upper respiratory tract infections and oral candidiasis. Other common reported adverse reactions include tinea infections, ear infections, herpes simplex infections, oropharyngeal candidiasis, gastroenteritis, folliculitis, headache, rash, dermatitis, eczema, acne, injection site reactions, fatigue, and vulvovaginal mycotic infection (including vulvovaginal candidiasis).[4]

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These data are from different clinical trials and cannot be directly compared.

Co-primary endpoints PASI 90 and IGA 0/1 at Week 16 were met.**Secondary endpoints. †N= mNRI, missing data were imputed with mNRI (patients with missing data following treatment discontinuation due to lack of efficacy or a TRAE were counted as non-responders; multiple imputation methodology was used for other missing data). ‡43.9% (n=189/431), and 43.4% (n=116/267) of biologic-naïve and TNFi-IR PsA patients achieved the primary endpoint of ACR 50 at Week 16 in BE OPTIMAL and BE COMPLETE, respectively (vs 10.0% [n=28/281] and 6.8% [n=9/133] placebo, p<0.0001); 54.5% (n=235/431) and 51.7% (n=138/267) maintained it at Week 52 (NRI).[4–6]

ACR 50, ≥50% response in the American College of Rheumatology criteria; **AS**, ankylosing spondylitis; **CRP**, C-reactive protein; **DMARD**, disease-modifying antirheumatic drug; **HS**, hidradenitis suppurativa; **IGA**, Investigator's Global Assessment; **(m)NRI**, (modified) non-responder imputation; **MRI**, magnetic resonance imaging; **nr-axSpA**, non-radiographic axial spondyloarthritis; **NSAID**, non-steroidal anti-inflammatory drug; **PASI 75/90/100**, ≥75/90/100% improvement from baseline in Psoriasis Area and Severity Index; **PsA**, psoriatic arthritis; **PsD**, psoriatic disease; **PsO**, psoriasis; **TNFi-IR**, tumour necrosis factor-α inhibitor – inadequate responder; **TRAE**, treatment-related adverse event.

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