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| 方案编号：  Registration number： | XK20190915QIU |
| 注册时间：  Date of Registration： | 2019-12-10 |
| 注册题目： | 评价人工智能眼疾筛查系统（AI-100）基于彩色眼底照片进行眼疾风险分析的有效性：前瞻性、配对、多中心、目标值法临床试验 |
| Public title： | To evaluate the effectiveness of artificial intelligence eye disease screening system (ai-100) for eye disease risk analysis based on color fundus photos: a prospective, paired, multicenter, target value clinical trial |
| 注册题目简写： |  |
| English Acronym： |  |
| 研究课题的正式科学名称： | 评价人工智能眼疾筛查系统（AI-100）基于彩色眼底照片进行眼疾风险分析的有效性：前瞻性、配对、多中心、目标值法临床试验 |
| Scientific title： | To evaluate the effectiveness of artificial intelligence eye disease screening system (ai-100) for eye disease risk analysis based on color fundus photos: a prospective, paired, multicenter, target value clinical trial |

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| 申请注册联系人： | 李雅庆 | 研究负责人： | 张秀兰 |
| Applicant： | Yaqin Li | Study leader： | Xiulan Zhang |
| 申请注册联系人电话：  Applicant telephone： | +86-10050819156 | 研究负责人电话：  Study leader's telephone： |  |
| 申请注册联系人传真 ：  Applicant Fax： |  | 研究负责人传真：  Study leader's fax： |  |
| 申请注册联系人电子邮件：  Applicant E-mail： | liyaqin@baidu.com | 研究负责人电子邮件：  Study leader's E-mail： | zhangxl2@mail.sysu.edu.cn |
| 申请单位网址(自愿提供)：  Applicant website(voluntary supply)： |  | 研究负责人网址(自愿提供)：  Study leader's website(voluntary supply)： |  |
| 申请注册联系人通讯地址： | 北京市海淀区西北旺东路10号院 | 研究负责人通讯地址： | 广东省广州市先烈南路54号 |
| Applicant address： | No.10 Xibeiwang East Road, Haidian District, Beijing, China | Study leader's address： | 54 Xian Lie South Road, 510080 Guang Zhou， Guang Dong, China |
| 申请注册联系人邮政编码：  Applicant postcode： | 100193 | 研究负责人邮政编码：  Study leader's postcode： | 510080 |
| 申请人所在单位： | 北京百度网讯科技有限公司 | | |
| Applicant's institution： | Beijing Baidu Netcom Science Technology Co., Ltd. | | |

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| 是否获伦理委员会批准： | 是 | | |
| Approved by ethic committee： | Yes | | |
| 伦理委员会批件文号：  Approved No. of ethic committee： | 2019QXPJ005 | 伦理委员会批件附件：  Approved file of Ethical Committee： |  |
| 批准本研究的伦理委员会名称： | 中山大学中山眼科中心医学伦理委员会 | | |
| Name of the ethic committee： | Zhongshan Ophthalmic Center Review Board | | |
| 伦理委员会批准日期：  Date of approved by ethic committee： | 2019-12-31 | | |
| 伦理委员会联系人： | 颜彦杰 | | |
| Contact Name of the ethic committee： | Yanjie Yan | | |
| 伦理委员会联系地址： | 广东省广州市先烈南路54号 | | |
| Contact Address of the ethic committee： | 54 Xian Lie South Road, 510080 Guang Zhou， Guang Dong, China | | |
| 伦理委员会联系人电话：  Contact phone of the ethic committee： |  | 伦理委员会联系人邮箱：  Contact email of the ethic committee： |  |

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| 研究实施负责（组长）单位： | 中山大学中山眼科中心 |
| Primary sponsor： | Zhongshan Ophthalmic Center, Sun Yat-Sen University |
| 研究实施负责（组长）单位地址： | 广东省广州市先烈南路54号 |
| Primary sponsor's address： | 54 Xian Lie South Road, 510080 Guang Zhou, Guang Dong, China |
| 试验主办单位(项目批准或申办者)：  Secondary sponsor： | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | 国家： | 中国 | 省(直辖市)： | 北京 | 市(区县)： | 北京 | | Country： | China | Province： | Beijing | City： | Beijing | | 单位(医院)： | 中山眼科中心 | 具体地址： | 广东省广州市先烈南路54号 | |  | | Institution hospital： | Zhongshan Ophthalmic Center | Address： | 54 Xian Lie South Road,510080 Guang Zhou,Guang Dong, China | |  | |

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| 经费或物资来源： | 北京康夫子科技有限公司 |
| Source(s) of funding： | Beijing Kangfuzi Technology Co., Ltd |
| 研究疾病： | 糖尿病视网膜病变、青光眼病变、黄斑区域病变 |
| Target disease： | Diabetic retinopathy, Glaucoma suspect, Macular Degeneration |
| 研究疾病代码： |  |
| Target disease code： |  |
| 研究类型： | 前瞻性研究 |
| Study type： | Prospective study |
| 研究所处阶段： | 其它 |
| Study phase： | N/A |
| 研究目的： | 试验采用前瞻性、配对、多中心、目标值法试验设计。试验目的是通过与中心阅片对比，评价试验用医疗器械“人工智能眼疾筛查系统”基于彩色眼底照片进行眼疾风险分析的有效性。 |
| Objectives of Study： | The experiment was designed by prospective, paired, multicenter and target value method. The purpose of the experiment is to evaluate the effectiveness of the "artificial intelligence eye disease screening system" for eye disease risk analysis based on color fundus photos. |
| 药物成份或治疗方案详述： |  |
| Description for medicine or protocol of treatment in detail： |  |
| 研究设计： |  |
| Study design： |  |
| 纳入标准： | 在 “人工智能眼疾筛查系统”中进行眼底彩照阅片，年纪 18-91 岁的受检者。 |
| Inclusion criteria | In the "artificial intelligence eye disease screening system", fundus color photos were read, and subjects aged 18-91 years were examined. |
| 排除标准： | 1. 视网膜脱离患者； 2. 眼底彩照不通过阅片中心质量审核者； 3. 因任何原因不能配合检查之受检者； 4. 受检者拒绝。 |
| Exclusion criteria： | 1．Patients with retinal detachment  2. Fundus color photos fail to pass the quality audit of scan reading center 3. Unable to give informed consent; and  4. Refused to receive colonoscopy. |

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| 研究实施时间：  Study execute time： | From 2020-04-16 To 2020-10-21 | 征募观察对象时间：  Recruiting time： |  |

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| 研究实施地点：  Countries of recruitment and research settings： | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | 国家： | 中国 | 省(直辖市)： | 广东 | 市(区县)： | 廈門 | | Country： | China | Province： | Guangdong | City： | Xiamen | | 单位(医院)： | 中山眼科中心 | 单位级别： | 三級甲等 | | | | Institution hospital： | Zhongshan Ophthalmic Center | Level of the institution： | Tertiary A | | |  |  |  |  |  | | --- | --- | --- | --- | |  |  |  |  | | |
| 测量指标：  Outcomes： | | |  |  |  |  | | --- | --- | --- | --- | | 指标中文名： | 灵敏度，特异度 | 指标类型： | 主要指标 | | Outcome： | Sensitivity and Specificity | Type： | Primary indicator | | 测量时间点： |  | 测量方法： |  | | Measure time point of outcome： |  | Measure method： |  | | |

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| 采集人体标本：  Collecting sample(s)  from participants： | |  |  |  |  | | --- | --- | --- | --- | | 标本中文名： | 无 | 组织： |  | | Sample Name： | N/A | Tissue： |  | | 人体标本去向 | 其它 | 说明 |  | | Fate of sample： | Others | Note： |  | |

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| 征募研究对象情况：  Recruiting status： | 已完成  Completed | 年龄范围：  Participant age： | |  |  |  | | --- | --- | --- | | 最小 Min age | 18 | 岁 years | | 最大 Max age | 91 | 岁 years | |
| 性别： | 男女均可 | Gender： | Both |
| 随机方法（请说明由何人用什么方法产生随机序列）： |  | | |
| Randomization Procedure (please state who generates the random number sequence and by what method)： |  | | |

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| 是否共享原始数据：  IPD sharing | 否 No |
| 共享原始数据的方式（说明：请填入公开原始数据日期和方式，如采用网络平台，需填该网络平台名称和网址）： |  |
| The way of sharing IPD”(include metadata and protocol, If use web-based public database, please provide the url)： |  |
| 数据采集和管理（说明：数据采集和管理由两部分组成，一为病例记录表(Case Record Form, CRF)，二为电子采集和管理系统(Electronic Data Capture, EDC)，如ResMan即为一种基于互联网的EDC： | 电子采集和管理系统（Electronic Data Capture, EDC） |
| Data collection and Management (A standard data collection and management system include a CRF and an electronic data capture： | Electronic Data Capture, EDC |
| 数据与安全监察委员会：  Data and Safety Monitoring Committee： | 暂未确定/Not yet |